IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

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IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL CASES	:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

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June 29, 2016

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Deposition of TIMOTHY B. McKINNEY, M.D., taken at the Hilton Garden Inn, 1885 Route 70 W., Lakewood, New Jersey, commencing at 9:11 a.m., on the above date, before CONSTANCE E. PERKS, CRR, CLR, CRC, RSA, a Federally-Approved Certified Court Reporter and Notary Public.

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I N D E X

WITNESS: TIMOTHY B. McKINNEY, M.D.

- - -

E X H I B I T S

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DEPOSITION SUPPORT INDEX

Direction to Witness Not To Answer
Page Line Page Line
(None)

Request For Production of Documents
Page Line Page Line
(None)

Stipulations
Page Line Page Line
(None)

Questions Marked
Page Line Page Line
(None)

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TIMOTHY B. McKINNEY, M.D., after having been duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. ORENT:

Q. Good morning, Doctor. How are you this morning?

A. Fine.

Q. My name is Jonathan Orent and I represent the plaintiffs in this matter, and I'm going to be asking you some questions today.

First of all, you've been deposed before; is that correct?

A. That is correct.

Q. Approximately, on how many occasions have you been deposed?

A. Probably around a dozen. Maybe a little less.

Q. Okay. And so you know the rules of deposition, correct?

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A. Yes.
Q. And just to refresh your recollection, if at any time you do not hear me or do not understand a question, will you agree to ask me to repeat or rephrase the question?
A. Yes.
Q. Okay. And likewise, if you do answer a question, is it fair for me to conclude that you understood the question that was asked of you?
A. Yes.
Q. And you're doing a great job so far, but just to remind you to answer with a yes or no, rather than a nod or shake of the head. Fair enough?
A. Yes.
Q. Okay. If you need a break at any time, just let me know and I'm happy to accommodate you. Okay? If there is a pending question, I would just ask that you answer the pending question and we can accommodate your break. Is that fair?

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A. Yes.
Q. And Doctor, would you just state your full name for the record.
A. Timothy Brian McKinney.
Q. Okay.
- - -
(Notice to Take Deposition of Dr. Timothy McKinney, marked for identification as Exhibit No. 1.)
- - -
(Curriculum Vitae of Timothy Brian McKinney, M.D., marked for identification as Exhibit No. 2.)

BY MR. ORENT:
Q. Now, Dr. McKinney, I've handed you what's been marked as Exhibit 1 to today's deposition, which is a copy of the Notice of Deposition for today. Have you seen this document before?
A. Yes, I have.
Q. Okay. And if you look, starting at page 4, there are requests to

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produce a set of documents. Did you bring any documents with you?
A. Yes.
MR. MORIARTY: That thumb drive has reliance materials for TVT General and for Maxwell.
MR. ORENT: Okay. TVT General or -- or Gynemesh General?
MR. MORIARTY: TVT General. That's what we're here to talk about. He was deposed on Gynemesh PS in Wave 1 for about three hours from a gentleman from Colorado.
MR. ORENT: And could we go off the record for just one moment?
MR. MORIARTY: Sure.
(Discussion off the stenographic record.)
(Deposition recessed from 9:14 a.m. until 11:40 a.m.)
BY MR. ORENT:
Q. Good morning again, Doctor. You're here now on your General TVT

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report, correct?
A. Yes.
Q. Okay. And we've previously marked as Exhibit A a copy of your -- the Notice of Deposition today and as -- excuse me, as Exhibit 1 a notice of your deposition and as Exhibit 2, I believe, is a copy of your CV; is that correct?
A. Yes.
Q. Okay. And you have a copy of your General TVT report in front of you, as well?
A. I do.
Q. Now, Doctor, in your report, you note that you have a long history of using the TVT; is that correct?
A. Yes.
Q. You started using the TVT in what year?
A. First year it was able to be done. I believe that was in '98.
Q. Okay. And you subsequently published in 1999. You worked on the -- the Ulmsten article; is that right?

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A. I worked on a -- the first North American exposure experiences with TVT.
Q. And Doctor, you used the TVT device before there was established data on its long-term safety; true?
A. I was in the first wave of people using it.
Q. And Doctor, when you first started using the TVT, did you tell your patients that there was no long-term data on the device?
A. Discussed with them a lot of the -- the preliminary data and where it was going.
Q. In 1998, where was the data going?
A. It had seemed that on short-term data that it was very efficacious and minimally invasive and was at least as good as the results that had been coming out. And the whole reason why I ended up getting into this field was because there was so little

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evidence-based medicine that was out there.
Bergman in 1995 was the first person to ever publish any kind of prospective randomized trials looking at incontinence procedures, and there were about 160 procedures at the time, but his five-year data in 1995 on the anterior Kelly plication, the Raz/Stamey Pereya type of urethropexy and then the Burch, that data came out and was rather surprising to the world that -- the standard of care at the time for incontinence was Kelly plication, which had a -- about a 37 percent five-year success rate of not leaking and --
Q. If I might just cut you off, Doctor --
A. -- a 42 --
Q. -- my question was relative to the data on the TVT, itself. You would agree that there was no long-term data at the time that you implant -- that you started using it,

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correct?
A. There was no long-term data for too many procedures that were out there being done for incontinence. That's why I brought up that aspect. But I had been -- the Integral Theory had been looked at. I had been privy to be able to talk to Ulmsten privately as well as personally for several reasons. One was that I utilized him for helping me develop my urodynamic pressure catheter back in the middle '90s, and so I got to be in his lab and see exactly what went on within -- with the development of this project.
Q. But again, in 1998, did you tell your patients that you didn't know what the long-term impact of having polypropylene mesh in the vagina was?
A. By that time, there would have been a number of uses of polypropylene, as well as other graft materials through the years for use for

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reconstruction, as well as incontinence, had been exposed to in my clinical training. My offspring was -- had been -- or I was trained by -- trained by Ostergard who is a huge Gore-Tex person. There was a lot of Mersilenes. There were a lot of looking to see what would be the better of materials that were out there, and it became obvious that the polypropylene, at least, was an inert and -- and a better material than some of the other woven materials that were given or the Gore-Tex, which was rather caustic.
Q. Well, I want to just focus on the question that I asked you, Doctor. And with regard to the TVT device, when you started using it, did you tell patients, specific to that device, that you did not know what the long-term safety or efficacy was?
A. For polypropylene? It had been used for years and years and years. I had been utilizing it for hernia

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repairs. So it's been -- it had been in my hands and used with a comfort level for more than probably -- may -- maybe some of my other people that may have started using it, but from my hands I had been with prop -- polypropylene for years and years.

Q. I understand that that's your position, but my question was specific to the TVT. Did you tell your patients that you did not know what the long-term outcomes in terms of safety or efficacy were with regard to the TVT device when you started using it in 1998?

A. I looked at the initial data that came out from Ulmsten's group and it had very little in the line of complications in comparison to the vertex pubic urethral --

Q. Doctor, that's not an answer to my question, and I'm going to move to strike that prior answer.

Doctor, my question was: Did you tell your patients, yes or no,

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that you did not know what the long-term safety or efficacy was related to the TVT in 1998?

A. I had told them that this was a new procedure that was being looked at as being at least as good as a more invasive procedure and that there were -- the results were utilizing a Prolene permanent hernia mesh type of material, which was a Type I large pore material, and that it had been -- multiple other materials had been looked at by this same group to finally formulate which material they felt was going to be less problematic. So --

Q. All right. Doctor, I'm going to cut you off, because, again, that's not an answer to my question.

My question was: Did you tell your patients in 1998 that you did not know the long-term safety or efficacy of the TVT device?

MS. GERSTEL: I'm going to object. Asked and answered.

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THE WITNESS: I didn't talk to them about the long-term efficacy of the procedure.

BY MR. ORENT:

Q. And there was no long-term data on the procedure, correct?

A. There was short-term data.

Q. And did you tell them that there was no long-term data on the efficacy of the procedure?

MS. GERSTEL: Objection; asked and answered.

THE WITNESS: I'm not sure whether I really understood any major efficacy problems, so no.

BY MR. ORENT:

Q. And did you tell them about the potential for long-term complications or long-term de novo complications following the procedure?

A. I talked to --

MS. GERSTEL: Objection; asked and answered.

THE WITNESS: I talked to

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them about all the complications of any of my surgical procedures for incontinence, which had the whole litany of complications which included recurrence, suture or damage to bowel, bladder, ureters, erosion of the materials that I utilized into the urethra or -- or bladder or both and --

BY MR. ORENT:

Q. Did you tell the patients that you did not know the complication rates?

A. Not on the specifics on -- with the -- the one centimeter thick -- wide mesh material, but --

Q. Did you tell the patients in 1998 that there was no data yet establishing what the long-term complication rates were for this device?

A. There were --

MS. GERSTEL: Objection; asked and answered.

THE WITNESS: There were

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short-term complications rates were -- which were very minimal.
BY MR. ORENT:
Q. Did you tell them that it was unknown what the long-term complication rates were?
MS. GERSTEL: Objection; asked and answered. To the extent you're looking for a yes or no answer, he's already answered the question.
BY MR. ORENT:
Q. Go ahead.
A. No.
Q. And Doctor, you would agree with me that in the most recent 17-year study, in fact, between years 11 and 17, the two most recent Nilsson studies, new complications were actually found, correct? There was new erosion between year 11 and 17?
MS. GERSTEL: Object to form.
THE WITNESS: It was more of

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a definition that was splitting hairs to try to determine or -- a better way to look at the different ways of expressing; was it an erosion, was it an exposure, did the skin break down, did it actually erode into a structure? So there were -- there was more of a -- an expansion of the one term that we used --
BY MR. ORENT:
Q. Well, you would agree that --
A. -- which was erosion.
Q. You would agree that there was a new reported complication?
A. It wasn't a new reported complication; it was an expansion of the -- the old definition and divided into two different categories.
Q. Well, it previously didn't appear in the data tables, correct?
A. It was a -- under a comprehensive title.

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Q. Do you agree, yes or no, did it appear on the data tables in the year 11 study versus the year 17 study where it did appear?
MS. GERSTEL: Objection --
THE WITNESS: I think --
MS. GERSTEL: -- he's already answered.
THE WITNESS: -- then, again, it was -- the data was all within the one definition, and it became a secondary additional split of the -- the data.
BY MR. ORENT:
Q. Doctor, did you have any work relative to participating in that 17-year study?
A. I did not.
Q. So this is your interpretation of the two studies, correct?
A. That is correct.
Q. You have no independent knowledge, correct?

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A. Other than what I've read.
Q. What have you read?
A. Just the paper.
Q. Okay. So what I'm saying is, aside from the studies, themselves, you have no other knowledge that informs you on these two studies?
A. That is correct.
Q. Okay. In your report, Doctor, is it fair to say that you do not rely upon any of the internal documents of Ethicon to determine what Ethicon knew at any point in time?
MS. GERSTEL: Object to the form.
THE WITNESS: I'm a little confused on that, but in the time of 1998 --
BY MR. ORENT:
Q. No. What I'm asking is: Just generally speaking, Doctor, as you sit here today, do you have any opinions relative to what Ethicon knew at any particular point in

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time relative to mesh and mesh complications?
MS. GERSTEL: Object to the form.
THE WITNESS: Do I have a --
BY MR. ORENT:
Q. So, Doctor, let me ask it a different way. You don't cite in your primary report on TVT any internal corporate documents, correct?
A. That is correct.
Q. And Doctor, is it fair to say that you will not be offering any opinions as to the state of the corporate knowledge inside Ethicon at any point in time?
MS. GERSTEL: Object to the form.
THE WITNESS: I mean, I've read a lot of the internal documents. I didn't find it necessary to end up putting it in in my defense of the actual procedure, itself --

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BY MR. ORENT:
Q. Well --
A. -- as it is the gold standard. It has definitely a much stronger efficacy and safety profile than the existing procedures that are out there for incontinence and --
Q. Again, Doctor, I just -- we're under a limited time and so --
A. Yes.
Q. I'm only allowed to ask you two hours worth of questions.
A. Correct.
Q. You tend to be -- I know you're trying to be helpful, but if you could just focus on the question that I'm asking. They're very precise questions, and if you could focus on them, it would allow us to get through much more material in the short period of time and prevent me from having to go to the court or ask defense counsel for an extension over the two hours. Okay?
MS. GERSTEL: Object to the

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form.
BY MR. ORENT:
Q. So now, Doctor, are you intending on testifying on any opinions that you have formed based on the corporate documents that you have reviewed?
A. Not in this.
Q. So, fair to say that you will not be offering any opinions on corporate knowledge of Ethicon at trial in this case?
MS. GERSTEL: Object to the form.
THE WITNESS: I'm not going to be... I mean, as it pertains to my other opinions that I have about the -- the company's participation and what they tried to do to end up bringing the best products to market and all the work that they went through to try to end up seeing the best product make it to market, I think that's

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part of my ability. But if you're trying to say am I going to comment on all the internal makings of the company, I think the company would be better off saying something about it.
BY MR. ORENT:
Q. And you don't cite any documents, corporate documents, in this report, correct?
A. That's correct.
Q. Now, Doctor, how long did you spend in drafting this particular report?
A. A lot of time.
Q. And what's that, 100 hours, 200 hours?
A. No. I don't know. Probably less than 50.
Q. Okay. And in that time, how much of that time of that less than 50 hours was spent -- do you think it's closer to 40 or 50?
A. 50.

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Q. In approximately 50 hours of time -- first of all, have you billed Ethicon yet?
A. I have not.
Q. Have -- how much of that time was spent reviewing literature?
A. It was kind of interspersed in there, but a good amount of -- over half.
Q. Okay. And how much time was spent reviewing corporate documents?
A. It was more earmarked towards the things that I thought were important within the documents that I'd need to know.
Q. Fair to say that you spent minimal time looking at corporate documents?
MS. GERSTEL: Object to the form.
THE WITNESS: I still spent time in there, yes.
BY MR. ORENT:
Q. But you would agree that

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that would be minimal time?
A. It was --
MS. GERSTEL: Objection.
THE WITNESS: -- less time than some other aspects to it, but yes, there were time spent, IFUs and other --
BY MR. ORENT:
Q. And you're making a very valid distinction. I'm not including IFUs in what I call corporate documents. I think that those are discussed in your report. So --
A. You mean looking at emails and all the little nuances --
Q. I'm looking at -- talking about emails and PowerPoints and some of the other documents that are listed as reliance material in some of your reports.
A. I looked through some of them in cursory and what counsel pointed out to me as well.
Q. Okay. Are you relying upon

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any of the material that counsel pointed out to you?
A. Am I relying on it to --
Q. Support your opinions.
A. -- make my opinion?
Q. Yes.
A. Other than that I thought that they've done a banner job of putting their product together.
Q. Well, I guess -- I'm entitled to ask you questions on what you're going to be offering at trial. Are you going to be talking about emails at trial?
MS. GERSTEL: Object to the form.
THE WITNESS: Only if really pushed into it.
BY MR. ORENT:
Q. So as you sit here, you don't intend on doing it, correct?
A. I don't intend to unless I'm --
Q. Okay.

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A. -- pushed.
Q. The only Ethicon written documents that you intend on relying upon are the instructions for use?
A. That would be a --
MS. GERSTEL: Objection.
THE WITNESS: -- a high probability.
BY MR. ORENT:
Q. Okay. Now, we can both agree you're not a regulatory expert, correct?
A. I am not, but I do have experience with that because of my company creating IFUs, creating CRs. Unfortunately, it's a part of business.
Q. Okay. Are you going to be offering opinions relative to the 510(k) process versus a premarket approval?
A. Not heavily, no.
Q. Okay. You're aware that there is a difference, correct?
A. Yes.

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Q. And you're aware that mesh is 510(k), correct?
A. That is correct.
Q. And mesh does not have the TVT, TVT-O, or other mesh devices do not have FDA approval, correct?
MS. GERSTEL: Object to form.
THE WITNESS: They've gone through scrutiny from the FDA, and so they have -- have obviously looked at them well enough to give their okay.
BY MR. ORENT:
Q. Well, you're aware that the 510(k) process that these devices went through is not a -- does not evaluate the safety or efficacy of the device, correct?
MS. GERSTEL: Object to form.
THE WITNESS: Well, they've gone back and are asking for more data, although the company has

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produced a lot of data to the FDA in response to the cytoxicity --
BY MR. ORENT:
Q. Right. Right. But, again, my --
A. -- and efficacy of the --
Q. My question's about the process and the initial process. You're aware that 510(k) as a process does not evaluate the safety and efficacy of a device, it compares it to a predicate device, correct?
MS. GERSTEL: Objection.
THE WITNESS: SME, too.
BY MR. ORENT:
Q. And the premarket approval process or the PMA process looks at safety and efficacy of devices and results in approval, correct?
A. Yes, sir.
Q. Okay. Now, Doctor, you're not a pathologist, correct?
A. That is correct.

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Q. You're not a biomedical engineer, correct?
A. That is correct.
Q. You're not an expert in material science, correct?
A. Correct.
Q. You're not an expert in the design of meshes, correct?
A. Correct.
Q. You're not a labeling expert, correct?
A. Correct.
Q. And you're not a warnings expert, correct?
A. Correct.
Q. You discussed pore size to some degree in your report. Are you an expert on what the ideal pore size is for transvaginally-placed midurethral slings?
A. Just from papers that I've read. The Ahmed report was probably one of the first ones that really looked over and quantitated and -- and discussed the different categories for what meshes were

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and was really driven towards the -- the Type I mesh being better versus a Gore-Tex. We kind of got it by trial and error, unfortunately, because a lot of docs like Ostergard had put in tons of them and taught us to put in other graft materials and Mersilene and --
Q. You would agree, though, Ahmed -- Ahmed -- you're referring to the 1997 Ahmed, right?
A. Yes.
Q. And you would agree that that was in relationship to hernia mesh, correct?
A. It was.
Q. Okay. And in terms of vaginal mesh, there's never been a publication or at least pre -- strike that.
What publications are you aware of that state what the ideal pore size is for vaginally-placed meshes?
A. The initial work was Ahmed. It was basically characterizing every

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single one of the graft materials that are out there. I think I -- something that I looked at, the vaginal -- I think I talked a little bit more about like a Falconer study, which had looked at TVT materials, itself, in relationship to other reactive tissues --

Q. Would --

A. -- including cadaveric fascia, and that TVT material was more elastic and better suited for vaginal placement. I'm -- I'm not -- I'm not the -- I'm not seeing anything other than Falconer's and --

Q. Now, Doctor, in preparing your report here, did you do a literature search specific to pore size to opine what the appropriate pore size for a vaginal mesh should be?

A. I did not find anything, no.

Q. You did not find anything. Did you actually go about and do a search for material specific to vaginal mesh pore size?

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A. I did not.

Q. Okay. Would you agree with me, Doctor, that you are not an expert on vaginal mesh pore size?

MS. GERSTEL: Object to the form.

THE WITNESS: I'm just a -- familiar with the general pore size for hernia mesh materials utilized within the body.

BY MR. ORENT:

Q. Now, Doctor, in your report, you don't state anything about ideal mesh density; is that correct?

A. I do not.

Q. Okay. And would you agree you're not an expert on the ideal mesh density?

A. Right at present, I'm not sure whether it exists today. We're still trying to end up getting a better product out there.

Q. But you would agree that you, yourself, are not an expert on

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defining and identifying the ideal mesh density as you sit here today, correct?

A. Correct.

Q. In terms of fiber diameter, you agree with me, Doctor, that you are not an expert on the ideal fiber diameter of mesh?

A. I am not.

Q. In terms of tensilary strength, would you agree with me, Doctor, that you are not an ideal -- excuse me, you are not a mesh expert on the ideal tensilary strength of a vaginally-placed mesh?

A. I am not.

Q. Okay. Elasticity, would you agree with me that you are not an expert on the elasticity of vaginally-placed meshes?

A. I'm not.

Q. Doctor, I noticed -- aside from reference going back to 1999 and the first participation in the studies of vaginal meshes, would agree with me,

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Doctor, that you are not -- you have not done an extensive history into the research and the development of vaginal grafts from 1920s forward?

MS. GERSTEL: Object to the form.

THE WITNESS: I have read over the history aspect of it. I've, unfortunately, been living the experimental process, I think, that was going on. The way I was taught is totally different from what I would be doing today. I hope I've been involved in changing the course of history.

Why I went into this field, because there were all kinds of things being utilized because the guru at the time was saying that this is the way it should be done. And so I was almost brought up with the fact that if it was done that way, it should be done that way, and that was the Penn way.

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And if it was done at Mayo Clinic this way, you -- you should follow like a -- a robot. I challenged it.

BY MR. ORENT:

Q. Now, with regard to, though, the history and development of vaginal meshes and grafts, would you agree that you're not an expert in terms of the historical development of these devices and not going to be providing expert testimony in trial as to the historical development of devices preceding the TVT?

MS. GERSTEL: Object to the form.

THE WITNESS: Well, I've been able to talk to Ulmsten and his partner who had extensively looked at multiple different materials that they tried for their slings and what they had determined to be inappropriate materials all the way up until

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they came upon the -- the Type I Prolene, which they found was -- I think it was in 1994 was when they finally honed it in and said, This is the material that we're going to end up using because of the lesser of the -- the -- the risks than the Gore-Tex and the -- some of the other materials that were out there at the time, Mersilene and --

BY MR. ORENT:

Q. Now --

A. -- Marlex.

Q. -- are you going to be offering testimony on the historical development of meshes going back through time in terms of what was known in history in terms of erosion, when erosion was first learned of, when various informational pieces were known at various times, things that don't appear in your written report?

MS. GERSTEL: Object to the

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form.

THE WITNESS: Other than my own personal experiences with it and all my frustrations with that, I think that's all pertinent to my expert opinion on the materials used in the development and the staging of vaginal meshes.

BY MR. ORENT:

Q. Well, let's look at something specific then.

Are you to be offering opinions as to whether or not polypropylene -- whether bacteria can travel along polypropylene?

A. Just historically, I know that it's not a higher -- it's not a high probability in comparison to woven materials, that polypropylene is less likely to end up having that occur.

Q. Do you know what rates of -- of -- strike that.

Is there a race to the surface of bacteria? Have you heard that

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term before?

A. I have not, but --

Q. Fair to say that you haven't done an extensive search into the literature on bacterial wicking vis-à-vis polypropylene?

A. Wicking as far as polypropylene, it's less likely than some other materials that were out there --

Q. I understand that, but have you done an --

A. -- that were chosen for the vaginal use.

Q. Have you done an extensive literature search on that for preparation of your report?

A. Not extensive.

Q. Have you done any?

A. Not literature search. Just in the readings of the state of materials that were out there.

Q. And Doctor, in terms of degradation, you state in some opinions in your report that, I believe, you don't

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believe that you have ever seen degradation.

Doctor, are you going to be offering opinions at trial in this case that degradation does not occur?

A. Not to a clinically-relevant state at all, if any. I haven't seen it in thousands of mesh implantation cases through the years. I'm not seeing breakdown. I'm not seeing any in really the materials even that I've taken out.

Q. Doctor, do you know what -- when I say "degradation," do you envision like a physical breakdown? Is that what you're envisioning?

A. It comes in many forms.

Q. Do you understand that when in this litigation, generally speaking, people have been referring to degradation, they're referring to the division of or the degrading of a molecule into two separate molecules --

MS. GERSTEL: Objection.

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BY MR. ORENT:

Q. -- in the polypropylene chain?

A. I -- I don't -- I don't agree with that.

Q. You don't agree that that's what we've been talking about or you don't --

A. Oh, no.

Q. -- agree that that happens?

A. I don't agree, and there's some -- some controversy in the literature over that. And if it is existing, it's not showing up in a clinical manifestation after --

Q. All right.

A. -- and particularly in this case on a TVT, TVO -- T-O, there's millions of cases that have been done over a 17-year period, and there's no association with any kind of a breakdown cytotoxicity or any kind of problem in that way.

Q. Now, going back, though, so

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if you understand that degradation just is a -- so that we're on the same page, is a chemical alteration of the -- the molecules within the polypropylene, do you have an opinion to a reasonable degree of medical certainty whether or not that that occurs? I'm not asking about the significance. I'm asking whether it occurs.

MS. GERSTEL: Objection.

THE WITNESS: It is controversial in the human body.

BY MR. ORENT:

Q. And Doctor, would you -- are you going to be offering -- strike that.

Is this outside the area of your expertise, the molecular -- are you going to be talking about what happens in a molecular level with polypropylene?

A. No.

Q. Fair to say that you might only be talking about whether or not there are clinical impacts of degradation?

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A. That would be -- yes.

Q. And you're not going to be talking about whether or not it happens or not, but whether you see clinical impacts of it; fair to say?

MS. GERSTEL: Objection.

THE WITNESS: Clinical impacts, as well as whatever I've read.

BY MR. ORENT:

Q. Okay. Well, have you done an extensive literature search on degradation and polypropylene?

MS. GERSTEL: Object to form.

THE WITNESS: I've looked over a number of papers. I don't know whether it's a 100 percent complete, but I've read a number of them.

BY MR. ORENT:

Q. And Doctor, did you do these searches for these papers yourself?

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A. Some. Some were given to me.
Q. Okay. Did you start with Anderson's papers?
A. Not that far back.
Q. Okay. Do you know who Anderson is?
A. Yes.
Q. Okay. Did you look at any of Ethicon's internal documents on degradation?
A. Can't recall.
Q. Would you recall if Ethicon reported internally that degradation of Prolene occurred? Would that -- would you recall that if you had seen it?
MS. GERSTEL: Object to the form.
THE WITNESS: I can't recall.
BY MR. ORENT:
Q. Okay. How many -- how much time did you spend researching the issue of degradation?

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A. It's just the papers that I was able to read and looking at some of the -- even the more recent one just came out which determined that what looks like a degradation may not be and that the protein cracking is really just protein. Once you're able to remove that, the actual fibers are intact.
Q. So essentially, you remove the degradation layer, the fiber's intact?
A. Correct.
Q. Now, Doctor, with regard to these studies that you reference, and you reference the hundred RCTs relative to TVT, Doctor, did you perform any kind of meta-analysis on these studies?
A. I did not. I relied on the meta-analysis that was done by -- by the experts out there. Cochran, I think, is the -- the -- the largest one that I saw. That was on, I think, 71 or -- studies or 81 studies of about 12,000-plus patients.
Q. Now, Doctor, are you -- do you still use TVT?

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A. Yes.
Q. And --
A. Or did up until a couple months ago.
Q. And that's when you took your sabbatical?
A. That is correct. I may go back if I decide to go back into a private -- or a group practice where I have -- more -- more or less not have to worry about finances.
Q. Now, when you started using TVT in 1998 through the present, how many TVT or TVT-O procedures have you done? Can you estimate?
A. I don't know. Thousand plus.
Q. Now --
A. Do you -- would you consider that as in all midurethral slings? Because it's definitely thousands --
Q. Okay. Did --
A. -- because some hospital --

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I worked at four hospitals. Some hospitals only gave us the opportunity to use certain companies' products. So --
Q. So fair to say --
A. -- it's hard to break it down.
Q. Okay. Now, with regard to the Ethicon, fair to say then that you can't give the jury a scientific analysis of your own experience relative to TVT or TVT-O only?
MS. GERSTEL: Objection.
BY MR. ORENT:
Q. You haven't tracked the data on your patients?
A. Well, within -- because I'm in a university setting, we do track our -- our -- our paper -- our patients. The residents are kind of required to do that, and I have fellows. I have three fellows in female pelvic medicine and reconstructive surgery. First fellow started with me back in 19 -- imagine this, '98. It was a non-accredited

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fellowship. I now have a credited fellowship.
Q. So do you have a compilation of all that data in terms of what your own safety and long-term efficacy rates are?
A. I have. It's more -- like you said, it's over -- it does have more than one procedure involved with it.
Q. Fair to say that any of your own experiences that you'll be talking about are based on your own clinical impression rather than raw data?
MS. GERSTEL: Objection.
THE WITNESS: It's kind of both.
BY MR. ORENT:
Q. Well -- and Doctor, would it be fair to say that you haven't produced any data of your -- aside from your published study that you participated in with the first 95 patients to get TVT in North America, you -- you're

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not going to be presenting any actual data to the jury on your actual experience, correct?
A. I will not.
Q. Now, Doctor, do you know to a reasonable degree of medical certainty whether all polypropylenes are the same?
MS. GERSTEL: Objection.
THE WITNESS: I'm not sure what you mean. Polypropylene meaning the way in which it's created or presented as a mesh material or --
BY MR. ORENT:
Q. Right.
A. -- as a suture material or --
BY MR. ORENT:
Q. The substance. So is the chemical that's in polypropylene in, for example, a Boston Scientific product, is it the same polypropylene that's in an Ethicon?
MS. GERSTEL: Objection.

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THE WITNESS: I would imagine there are some differences.
BY MR. ORENT:
Q. Are you an expert on what those differences might be?
A. No.
Q. Do you know why antioxidant packages are put into polypropylene?
A. As far as prevention from exposures.
Q. And Doctor, do you have medical opinions or are you going to be presenting any opinions on why antioxidant packages are included in polypropylenes?
MS. GERSTEL: Objection.
THE WITNESS: No.
BY MR. ORENT:
Q. Okay. And likewise, you're not going to be presenting any opinions as to why Ethicon chose the polypropylene that it did or the particular type of antioxidants within the Ethicon

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polypropylene, correct?
A. I am not.
MS. GERSTEL: Objection.
BY MR. ORENT:
Q. Doctor, do you rely on any SEM imagery in forming your opinions in this case?
(Phone interruption.)
MR. ORENT: We can go off the record.
(Discussion off the record.)
MR. ORENT: Can you read back the last question?
(Reporter read back from the stenographic record.)
THE WITNESS: Can you give me the -- what the SEM --
BY MR. ORENT:
Q. Scanning electron microscopy.
A. Electron microscope, right. Not other than what's in papers.
Q. Are you going to be offering any opinions as to whether tissue ingrows

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into fractures within the polypropylene fibers, whether it's in vivo or whether or not the cracks are formed after excision?

MS. GERSTEL: Objection.

THE WITNESS: I -- I believe that there's a lot of changes that go on if you end up removing graft material, because there's a lot of trauma that can go on from trying to extract these materials, and then when you're ending up looking at them, there are -- are variations in it.

So from the standpoint of a generalized look at it, I'm going to be commenting that there are some reasons for that to be cracked.

BY MR. ORENT:

Q. Are you --

A. Am I the total expert on -- on it? Probability not.

Q. Now, Doctor, when you --

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when you do TVT or TVT-O procedures, do you use laser-cut or mechanically-cut mesh?

A. I'm not particularly sure which one it is. I imagine it's the environment or the country or whatever that the products were made in and shipped from or shipped to.

Q. Doctor, as you sit here today --

A. I'd say that it's not a laser cut.

Q. Doctor, with -- would you agree with me that as you sit here today, when you're performing surgery in the OR, you don't know which device you're being given, a laser-cut TVT or TVT-O or a mechanically-cut TVT or TVT-O?

MS. GERSTEL: Object to the form.

THE WITNESS: That is correct.

BY MR. ORENT:

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Q. Okay. And Doctor, would you agree that the instructions for use are the same for laser-cut and mechanically-cut TVTs and TVT-Os?

A. Yes.

Q. Doctor, do you have a -- an opinion -- do you know whether or not there are any mechanical differences between laser-cut and mechanically-cut TVT and TVT-O?

A. I don't have -- I don't believe there is any real difference in the -- the strength of the two slings.

Q. Again, that's the strength. And what do you base that on?

A. Just that I've not seen any differences, and I'm sure I've probably used both.

Q. Now, is this something that you've researched, the differences between mechanically and laser-cut TVTs and TVT-Os?

A. Other than what I've read or heard.

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Q. And what have you read or heard?

A. Just that there are really no major differences as far as the strength.

Q. Fair to say that you're not an expert on any differences that may exist between the two?

A. I am not an expert.

Q. And fair to say that if there are any differences, chemical or physical property differences, that you haven't been provided any information relative to that specific to finding -- to doing this report?

MS. GERSTEL: Object to the form.

THE WITNESS: Are you referring to anything along the lines of any potential little particles or anything coming off the -- the material?

BY MR. ORENT:

Q. No, no, I'm asking in terms

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of safety and efficacy profile. You've not seen any -- any --
A. Any --
Q. -- documents or medical studies discussing the difference between laser cut and mechanically cut, correct?
A. I think it would have come out in the -- the literature if there was a major difference. There would be -- the safety, efficacy, and success rates are pretty ubiquitous around the world. It's not something that's something strange and unique that one country has a terrible success rate and the other country that has laser cut has great results or just the opposite.
Q. Now, Doctor, have -- did you do a literature search to look at whether or not TVT and TVT-O have been compared, the laser cut to the mechanically cut, head to head?
A. I have not, other than I know that it's interspersed within different regions of the world, and --

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but the data that's out there, it's pretty much ubiquitous throughout the world and reported even in the European societies and regulatory aspects.
Like over in England, NICE, they still consider this is a gold standard procedure, as well as every single society in the -- the US, as well as the international societies, International Continence Society, International Urogyn Society [sic], NICE. It's -- the efficacy is there, the safety is there, and -- and you'd think that they would end up mentioning things like the different ways in which something was cut.
Q. Now, Doctor, you just referenced AUGS. You would agree with me that the AUGS statement is not a scientific statement, correct?
MS. GERSTEL: Object to the form.
BY MR. ORENT:
Q. It's -- it's a --

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A. It's a compilation of all their own analysis or meta-analysis of all their committees. They've looked over all the data that's out there and -- and are speaking as far as what they believe is the -- is their opinion on what would be available if slings weren't available.
They're talking about every bit of information that they've been able to get from SUFU, Society of Urodynamics and Female Urology, or now it's called Female Pelvic Medicine and Urogenital Reconstruction. They've expanded it because of the new fellowship training.
But all these societies, all this data, and have come up with their opinions and are reinforcing them as we speak, and there isn't a single society out there that had said, Oh, don't use this. They're saying this -- the slings are the gold standard. They far outweigh any of the other procedures that are out there, and if this gets interfered with,

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women's health will be set back decades.
Q. Now, Doctor --
MR. MORIARTY: It looks like you're about to launch into a long series of questions about this.
MR. ORENT: Yup.
MR. MORIARTY: Let's take five minutes.
MR. ORENT: Sure.
(Discussion off the stenographic record.)
(A recess was taken from 12:30 p.m. until 12:43 p.m.)
(Reporter read back from the stenographic record.)
BY MR. ORENT:
Q. Doctor, I'm going to mark and hand you Exhibit 3 to today's deposition.
- - -
(AUGS Position Statement, marked for identification as Exhibit No. 3.)
- - -

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BY MR. ORENT:
Q. That is the AUGS statement that you were referring to, correct?
A. When did this come out? This is the 14th. Yeah. There's actually an addendum on this that is --
Q. This year?
A. -- that I was privy to see just a day or two --
Q. Yes.
A. Coming to a neighborhood near you. It's pretty extensive, as well.
Q. The --
A. Doug Hale did -- did the letter. He's the president of AUGS.
Q. You would agree, Doctor, that this is not a peer-reviewed statement, correct?
A. It is a consensus statement on review of all the literature and it's done by a very reputable group that are probably the most scientific-minded people. There's -- AUGS members are at

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least 1500 strong. SUFU members, because this is a combined SUFU and AUGS society consensus, SUFU is about 500 of the top urologists in the world that are involved in SUFU.
So, yes, it is a -- it isn't a -- it is a scientific paper from the standpoint of review of the literature was exceedingly extensive.
Q. Well, this was not peer reviewed, correct?
A. We are --
MS. GERSTEL: Objection.
THE WITNESS: -- the peer reviews -- reviewers, I should say, so people -- most people that are on the editorial staffs and the boards throughout the world belong to these societies.
BY MR. ORENT:
Q. I understand that.
A. They write the -- they are the -- the review committees.
Q. But this did not go through

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a formal peer-review process, correct?
A. It's about as firm a peer review as you could possibly get --
Q. It's --
A. -- by way of looking at and reviewing all the papers that were peer reviewed and putting them together.
Q. Well, a literature summary piece, an academic piece that discusses literature and is published goes through a peer-review process just like original research, correct?
MS. GERSTEL: Object to the form.
THE WITNESS: That is correct.
BY MR. ORENT:
Q. And this did not go through a formal peer-review process, correct?
A. It went through the committee that makes up pretty much the board that reviews most of these papers.
Q. No.
A. So yes, it is a very

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heavily-scrutinized document and was painstakingly put through to be as thorough as possible.
Q. Well, now, Doctor, you say it went through committee. Who's on the committee besides the named authors?
A. Who's in the committee?
Q. Uh-huh.
A. There's probably about 30 docs.
Q. Who are they?
A. I can't name them right off the bat.
Q. What was the process in drafting this particular statement?
A. The process?
Q. Uh-huh.
A. It was looking over the literature, collecting and looking over, say, the Seratis, Nilssons, and -- and the -- the meta-analysis that was done by the Cochran studies, the -- you name it, it was put through and looked at to see if there was anything -- any -- where --

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where they should lie in their opinions on this.
Q. Did you have any personal involvement in this?
A. I did not, other than I got shown it before it got released --
Q. Now, Doctor, you're aware that --
A. -- as a member of AUGS.
Q. -- this was not voted on, correct?
A. It was not voted on. It was a -- a very strong committee which included the people that we had elected for that position.
Q. This was not an ad hoc group?
A. No, this is more of a committee that we had asked to end up reviewing and coming up with a statement, because we, as -- as AUGS members and SUFU members, which I'm a member of both -- it is very concerning to us that we may have to end up going back in time

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to doing procedures that are much more aggressive, much more harmful to our patients and -- and much more risky.
Q. Doctor, true or false, this was an ad hoc committee of volunteers?
MS. GERSTEL: Object to form.
THE WITNESS: It is a very strongly academic committee. Howard Goldstein, he's --
BY MR. ORENT:
Q. Doctor, that wasn't my question.
A. I'm looking at the names that are listed on here. They're --
Q. My question is, Doctor --
A. They're a task force, yes.
Q. -- the individuals who wrote this statement, did they volunteer or were they formed on a specific committee for purposes of this?
MS. GERSTEL: Object to the form.
THE WITNESS: I'm not a

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hundred percent sure of how they were ending up being selected into there, but it was not a very -- it was a very carefully selected group.
BY MR. ORENT:
Q. It wasn't an informal process?
A. It was -- if you want to call it informal. It was -- they weren't volunteered.
Q. Well, let me ask this --
A. They were asked into it by --
Q. -- Dennis Miller was a consultant for Boston Scientific; true?
A. He -- maybe.
Q. He invented the Pinnacle device; true?
A. He did.
Q. Made over five million dollars from Boston Scientific; true?
A. I have no idea.
Q. Howard Goldman works for

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AMS, correct?
A. He's a professor at Cleveland Clinic and is very reputable.
Q. He's consulted for AMS with their mesh, correct?
A. I doubt it.
Q. Okay. Are you aware, Doctor, that Dr. Goldman wrote letters to the editor against Dr. Ostergard's articles with Dr. Sternschuss?
A. I've --
MS. GERSTEL: Object to the form.
THE WITNESS: I've seen them.
BY MR. ORENT:
Q. Okay. Were you aware, Doctor, that AMS vetted that article and Dr. Goldman worked with AMS --
A. I know --
Q. -- and did not disclose that fact?
A. I know Cleveland --
MS. GERSTEL: Objection.

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THE WITNESS: -- Clinic's feeling of -- or any of the Cleveland Clinic people working for them is frowned upon. Let's put it that way. So I don't know what extent Dr. Goldman was able to end up participating knowing where he's from and how stringent they are at it. He does --
BY MR. ORENT:
Q. But --
A. He did not make any money, himself, from any kind of work that he would have done for AMS, if he did do anything other than consulting.
Q. So why did Dr. Goldman vet his letter to the editor to AMS's company before trying to get it published?
MS. GERSTEL: Objection.
THE WITNESS: I don't know.
BY MR. ORENT:
Q. Paul Tulikangas, which companies did he -- is he -- has he

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consulted for that make mesh?
A. I can't tell you.
Q. Can you tell me about Eric Rovner?
A. I can tell you that he's the chairman down in --
Q. MUSC, right?
A. -- North Carolina, Charlotte -- Charleston. Charleston.
Q. He's at MUSC.
A. Oh, okay.
Varied procedures. He was right underneath Alan Wein at Penn. That's when I got to know him a lot. He's president for SUFU or was and very, very difficult to end up having him give opinions, again, unless they're something strong. He's not a big --
Q. But you don't know as you sit here today which mesh companies he consulted for, correct?
A. I have no idea.
Q. Now, Doctor, you're aware there is a debate in the scientific

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literature about the safety and efficacy of mesh; you'll agree with that, correct?
MS. GERSTEL: Objection.
THE WITNESS: I -- I believe that you -- that's why all this is coming about, and --
BY MR. ORENT:
Q. Okay.
A. -- it's -- it's very bothersome to a lot of us that are seeing the risk factors going towards going back to a procedure that if you -- if you look at the sister trial, that's looking at the Burch and it's looking at the pubic -- pubourethral slings and a comparison, they had a nearly 60-some-odd percent complication rate with -- with the pubovesical slings and Burches. They're big incisions. They're problematic. They're -- they fail --
Q. I understand. I understand.
A. They had a 13 percent success rate --
Q. I understand that that's

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your position.
A. -- long term. And so --
Q. My question --
A. -- to go back to that off of one of these things is -- is like asking us to go back decades in advancement for women's health in particular, and it's --
Q. Well, Doctor, my --
A. -- very, very, very --
Q. -- my question is --
A. -- angering to everybody that's in AUGS, SUFU. I'm also involved in the international societies, IUGA.
Q. Well, Doctor, let me just back up then. You would agree -- my question is just solely this: You would agree with me that there are some very reputable urologists, gynecologists, and urogynecologists who oppose the use of transvaginal meshes?
A. That oppose it?
Q. Uh-huh.
A. I'm surprised at some of them right now that are opposed to it,

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because Ostergard put in the most amount of graft material and Gore-Tex because he had --

Q. I understand.

A. -- had money into --

Q. No.

A. -- that company.

Q. No. My -- my question's just --

A. There's a lot of --

Q. My question is solely: You would agree that there are some very well-respected, credentialed urologists, gynecologists, and urogynecologists who, for whatever reason, oppose the use of vaginal meshes; true?

A. Not in the line of slings. I don't know of -- maybe a couple of physicians, but I don't know how reputable they are at this point, because if they're challenging this and they know the data out there, there's a problem with them. If they're on your side and they're making a thousand dollars an hour

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and couple of thousand dollars for a deposition, I mean, it's -- it's problematic in my mind with the amount of literature that's out there that's supportive of midurethral slings. It's --

Q. There are.

A. It's staggering.

Q. There are. There is a body of literature, though, and would you agree not all midurethral slings are created equal?

A. There are different slings, yes.

Q. Some are better than others?

A. They're designed for different purposes.

Q. Well, would you agree that all retropubic slings are not the same?

MS. GERSTEL: Object to the form.

THE WITNESS: The position where they're going through is -- they're fairly -- designed for the

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most severe incontinence. They're the ISD patients. They have a little bit more positioning, and so there are some nuances in it.

BY MR. ORENT:

Q. I'm not asking patient to patient. I'm asking the sling material, itself. Is it your position that the safety and efficacy of one sling that's for -- designed for retropubic implantation is equivalent to all slings for --

MS. GERSTEL: Object to the form.

BY MR. ORENT:

Q. -- implantation --

A. The majority of them these days are Type I materials with large pore, monofilamentous, polypropylene and they are -- fall into that category. So as far as the category, they're all in that category. If there's little nuances on how they're -- they're put together, how they're cut, how they're done, that's

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-- that's a different realm, but these -- these are fairly consistent.

Q. Well, when you did your report, fair to say that you -- your opinions on TVT and TVT-O, broadly speaking, are relevant -- are designed as opinions related to all midurethral slings?

MS. GERSTEL: Object to the form.

THE WITNESS: There's more data on TVT and TVT-O than on a lot of these companies other -- other companies' slings.

BY MR. ORENT:

Q. Well, I guess my point is --

A. There's longer data, definitely.

Q. -- with regard to TVT-O, do you have opinions on the performance of TVT-O that are separate and aside from TVT? Have you pulled out complication rates specific to TVT-O?

A. I have.

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Q. And where are they in your report?
A. I'm not sure if they're listed directly as two separate entities, but they were both considered fairly comparable. I know I put it in there or read it.
Really, for the TVT-O, the only difference was a complication within the six months' period of potentially some groin pain with the TVT-O versus the retropubic approach, and there was less risks to the patients with TVT-O, and bladder perfs were -- even getting into the abdominal cavity's less risky from that standpoint.
Q. Doctor, would you agree that TVT and TVT-O have different risk profiles?
A. They have some different risk profiles, yes.
Q. Do you agree that IFUs are the same?
A. I believe that they are the

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same, yes.
Q. And the TVT-O IFU does not call out the specific potential complication of groin pain, correct?
A. It's pretty familiar from any doc wherever these things are going to --
Q. That wasn't my question, Doctor.
A. Whenever you're doing any kind of surgery, it's going to affect the area that it goes through. So one goes through suprapubically and one goes through the groin. If you've got a different surgical field that you're going through, it's going to have that extended normal complicating aspect, just like if you did a paravaginal defect repair, you're going to be going out into that obturator area and reattaching things. There's a risk of pain that's going to be associated with those muscles out there.
Q. Well, you -- you --

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A. That's the same with this.
Q. First of all, you would agree, though, that the specific nerve injury related to TVT-O was not referenced in the IFU, correct?
MS. GERSTEL: Objection.
THE WITNESS: It's a broad paint stroke that went on with the IFU, and obviously, with the newer IFU, the litany is like this. Why? Because of all the litigation, it's pushed them towards listing everything under the sun into them. And so it should be -- the IFU should be looking at just general aspects and writing out something that's not designed to be like everything that could possibly happen.
BY MR. ORENT:
Q. Well, urologists typically don't operate in the obturator space, do they?
MS. GERSTEL: Objection.

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THE WITNESS: They -- if they're dealing with any kind of incontinence, prolapse, or anything, yes, they -- they --
BY MR. ORENT:
Q. Not before the TVT-O, did they?
A. Burch.
Q. Going back historically, they did not operate in --
A. Burch, MMK.
Q. -- they didn't operate in the transobturator space, did they?
A. They were out there. Any hernia repairs, that's all out towards the obturator side of things. They're -- they darn well better know anatomy anyway --
Q. That wasn't my question.
A. -- all around the bladder.
Q. My question to you is very simply: Urologists, are they used to operating in the obturator space where the TVT-O goes prior to

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this?
A. It's -- it's -- everybody that is a surgeon understands the spaces that --
Q. That's not my --
A. -- the anatomical spaces that they're going through.
Q. -- not my question. Urologists --
A. Yes.
Q. -- before TVT-O --
A. They're surgeons.
Q. -- historically --
A. They're surgeons.
Q. -- did they operate in the transobturator space?
A. They've been in there.
Q. That's your opinion?
A. Yes.
Q. To a reasonable degree of medical certainty --
A. Yes.
Q. -- gynecologists --
A. Gynecologists --

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Q. -- traditionally did they operate in the transobturator space?
A. They probably didn't maybe know as much about it. They just said, Oh, we put some of this stuff to that stuff, but they were in the space. Whether they knew it or not is frustrating to me because I've taught a lot of them --
Q. And --
A. -- and they're in there, and they were all around it.
Q. And you don't think Ethicon should have warned them in a space that they weren't typically working in of the specific risk of nerve injury related to transobturator meshes?
A. I think they've --
MS. GERSTEL: Objection.
THE WITNESS: -- been educated long enough. They've gone through anatomy. They know it. They're a surgeon. They

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should know the anatomy in those spaces.
BY MR. ORENT:
Q. Now, Doctor, you would agree with me that the risk profile is different between the TOT and a TVT-O?
A. I'm sorry, repeat it again. I was still back --
Q. Would you agree with me that between a transobturator tape and the TVT-O, and in specific Ethicon, that there's a different risk profile, outside-in versus inside-out?
A. They're very similar.
Q. There's a different risk profile, complication rate, isn't there?
A. Minimal differences.
Q. Okay. It's a lot greater blind space going with the TVT-O approach, isn't there?
A. It all depends upon whether you've followed the guidelines of using the -- the little guide that goes in or whether you've decided to drop what

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they've given you to help with the placement of it. And there are surgeons that are -- I'd allow operating on you and surgeons that would allow to operate on my -- my significant family, and other ones that have deviation from the abilities.
Q. But I --
A. Unfortunately, not everybody is created equal as surgeons. There's knowledge, though, that everybody should have. When you graduate from school, you've gone through anatomy. You've had to pass the boards to know the anatomy in all those spaces. There's no excuse for you to not to, as a surgeon, whether you're a urologist, gynecologist, colorectal surgeon, not to know that space.
Q. The TVT-O was designed for ease of use, correct?
MS. GERSTEL: Object to the form.
THE WITNESS: It was

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designed to avoid the retropubic space which potentially -- while it had -- houses the bladder and potentially could house bowel in it, so it was to decrease the risks of any complications within that space. So -- and it was seen that the efficacy of it was equivalent for those patients in particular that did not have intrinsic sphincter deficiency --
BY MR. ORENT:
Q. And in --
A. -- on urodynamics.
Q. In terms of groin and thigh pain, avoiding injury from the TVT-O device, how does it compare in the literature between the outside-in and inside-out approaches?
A. It's fairly comparable, maybe slightly higher, but there's other groin pain that comes from the outside-in --
Q. Would you agree, Doctor --

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A. -- and a bigger dissection that you have to make for the outside-in, which leads to other complications of the procedure, which is that you're cutting some of the nerves around the urethra, which leads to a higher risk of intrinsic sphincter deficiency afterwards. It's --
Q. Doctor, would you agree with me that -- well, strike that.
Did you perform a comprehensive literature review to compare the TOT performance to the TVT-O --
MS. GERSTEL: Object to the form.
BY MR. ORENT:
Q. -- inside-out versus outside-in?
A. I've looked at that --
MS. GERSTEL: Object to the form.
THE WITNESS: -- in many years, multiple times over the years.

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BY MR. ORENT:
Q. And where in your report is that cited?
A. I probably -- it was a shortened period of time. I didn't probably put it in, and I probably could have.
Q. And would you agree with me, Doctor, that the erosion rates are different between TVT and TVT-O? I should say urethral erosion rates.
A. There is a minor increase.
Q. And by percentage points what is that?
A. One or two percentage points.
Q. And in some studies there's actually a doubling; is that right?
A. Depends upon -- I mean, it's rare to begin with, and so rare going to -- from .01 to .02 being a doubling, I guess you could say that it's right, but --
Q. Well, Doctor, did you --

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A. -- or up to 1 to 2.
Q. -- did you do a comprehensive literature review comparing TVT to TVT-O in terms of urethral erosion rates?
MS. GERSTEL: Objection; asked and answered.
THE WITNESS: I've -- I've looked at the two differences. Obviously, that's why you have -- TVT-O has been decreasing some of the -- the risk factors that you can experience with the retropubic approach; however, you need to pay attention more to the patient's diagnosis and you need to really pay attention to their urodynamic data, because there is a falling off of the success rate for an intrinsic sphincter deficiency patient if you're doing an obturator versus a retropubic approach.
BY MR. ORENT:

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Q. And that's not in the IFU, correct?
A. There is -- it is not necessarily spoken, and it's not something that they would have known even at the beginning of -- of these things. There -- and I have used a generalized look at things, at least when I've written it for myself and the products and -- and my company.
You -- you're not going to be able to mention everything out there. You got to count on doctors to actually have some brain about them and also to have to follow the literature, because it can change from month to month, year to year, and you're having to end up adjusting it.
Doesn't mean that you have to change the IFU. It's a major, major process to end up having to change an IFU. It's just a guideline to keep -- keep -- for the major use, not all the little details.

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Q. Now, Doctor, with regard to yourself and your practice, you're -- would you say that you're an advocate for use of mesh?
MS. GERSTEL: Object to the form.
THE WITNESS: Am I an advocate? In the right circumstances, absolutely.
BY MR. ORENT:
Q. And Doctor, you left your prior practice in September, correct?
A. It was weaning down, and I finally closed, closed it all by -- by December.
Q. You announced the retirement in September, correct?
A. Yes.
Q. And was that before you were retained by Ethicon in this case?
A. It was before.
Q. And between -- over the years, you've consulted for AMS and Ethicon, correct?

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A. I've consulted for many companies, yes.
Q. What other mesh manufacturers have you consulted for?
A. Boston Sci, Coloplast. Mostly just being asked to -- to -- on a consultant basis to look over a product that they have or something that they wanted to do. Remeex. I don't know what the name of the company is. That's another sling product with an adjustable sling. They ask me my opinions and I'll give it to them, and --
BY MR. ORENT:
Q. And over the years, how much money have you made consulting for mesh companies?
MS. GERSTEL: Object to form.
THE WITNESS: I really couldn't tell you, but it's not been huge.
BY MR. ORENT:
Q. In the six figures?

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A. Probably a little under.
Q. Now, Doctor, you've always been a pro-mesh guy, correct?
A. I have been a -- a pro-patient side, and I've grown -- I've been able to experience from going from my program where prolapse surgery was considered a success if everything was held inside. It didn't matter whether the patient peed on themselves, defecated on themselves, or had pain or had no vagina left. It was successful long as the doc looked at it and went, Ah, it's cured.
Very frustrating to me. I finished off my residency program, worked with Cullen Richardson on the anatomy just because I -- I felt like there was something different. And so myself, Al Bent, Rogers, there was a litany of high-end physicians. We got together, whoever had a cadaver, and we'd fly in, we'd look over the anatomy. And Cullen was a big firm believer that there

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were -- it was not stretched in attenuated tissue, it was tears and specific breaks in the endopelvic fascia creating hernias within the pelvic floor.

So with that information, we set out to look for ways of doing this. So we were putting together things using just those site specific, need of tissues. It gets frustrating when you start -- when you think you did the most incredible job and the person falls apart.

Q. You've been using mesh and have been a proponent of it since 1998, correct, or earlier?

A. Earlier.

Q. Okay. And going back to the AUGS statement, you'd agree with me that you don't really know the true way in which this position statement was adopted, correct?

MS. GERSTEL: Object to the form.

THE WITNESS: It was an

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extensive review and it was definitely passed around to us to -- as a society and utilized our feedback into them, which was extensive.

BY MR. ORENT:

Q. Well, Doctor, that -- this -- do you know -- there was no vote, correct?

A. There was a consensus within the meeting. There were definitely a lot of communications to them.

Q. So you're not disagreeing with me and the information that I'm aware of that says that there was no vote on this, correct? You're not disagreeing with that, are you?

A. There was no vote on it.

Q. Okay. And this was written by a single author and then passed around to some people for comment, correct?

A. I don't think --

MS. GERSTEL: Object to form.

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THE WITNESS: -- that it was a single author.

BY MR. ORENT:

Q. The initial draft --

A. There -- there are some letters that -- forthcoming afterwards from the president of AUGS that ended up with the help of all the committee members and whoever else he wanted to share with it, and -- and I -- I know several people that have gotten that information, edited it, passed it back to him to end up coming together with a formalized document at the end. It is not a one-person. It is one person acting as the spokesperson --

Q. I understand.

A. -- and that's the president.

Q. The first draft that was sent around, that was a single author, correct?

A. I have no idea. This is not the first draft.

Q. Right. And we're not --

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we're not --

A. And I don't know whether it's a single person that wrote that.

Q. Okay.

A. It was --

Q. Ultimately, it was signed onto by the individuals whose names are on there, correct?

A. It was signed on at least by the presidents of each of those societies, which is -- I would anticipate is in here.

Q. Now, Doctor, what negative comments and feedback did that receive before it was published?

A. I think for the most part, it was applauded.

Q. Did it receive some negative feedback to the authors before they finalized it?

A. I'm sure there was opportunity -- if you had an opinion that was a negative one, that there was plenty of open forum for your ability to talk

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about it.
Q. That particular statement, it doesn't list or discuss any complications related to mesh, correct?
A. It just talks about some of the safety and efficacy as compared to what other morbidities are out there.
Q. It doesn't discuss the complications, does it?
A. It doesn't go through specifically the -- the -- the individual papers and what came to their conclusion in there.
Q. And there's only between 10 and 14 articles cited, correct?
A. Within those articles are a compilation of multiple, multiple papers that are in -- involved in it. Other than Nilsson, I thought there -- they had that -- the Cochran 91 or some ridiculous number of peer-reviewed, randomized, controlled trials that were done that were put into that data.
Q. Now, Doctor, do you know

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whether or not only individuals who were for the use of mesh were provided a copy of this --
A. No.
Q. -- before it was released?
A. I'm sure it was given to everybody --
Q. You're sure --
A. -- and at that point --
Q. -- or you think?
A. I'm pretty sure.
Q. And what's the basis for being pretty sure?
A. Just that they were -- it's a very, very, very conservative society, both of them are, and they're not about to go sticking their neck out without approaching people of high quality that they believed would give their fair feedback on it.
Q. Well, again, just focusing on this particular statement, you don't have firsthand knowledge of that, do you?
A. I know that it was passed

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around, and I know --
Q. And you know that you received it, correct?
A. I've seen it, yes.
Q. You don't know who else received it, as you sit here today, correct?
A. I --
MS. GERSTEL: Object to the form.
THE WITNESS: Well, this one, it's -- it's -- everybody's got it.
BY MR. ORENT:
Q. Not before it was published?
A. Not before it was published.
Q. Before it was published, who else received it for comment besides you?
A. I'm not sure.
Q. And you've been -- when we talk about letting -- openness to patients, do you tell your patients -- do you believe in being fully open and honest about the potential permanent

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long-term complications of mesh with your patients?
A. Yes.
MS. GERSTEL: Object to form.
BY MR. ORENT:
Q. And what do you tell your patients about the controversy of mesh and the dangers of mesh?
A. I was giving them the FDA form. I was giving them the AUGS and whatever forms were out there. I also -- from day one, all my consent forms have everything listed in it. It's kind of scary to them because I -- I always start with death. I go death and then all the complications, infection, erosion, bleeding pain, persistent pain, dyspareunia, and -- and the --
Q. And --
A. -- litany goes on and on, and that's gone from probably the beginning when I left my residency program --

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Q. Well, Doctor, specific to mesh.
A. The only anything different for mesh would be erosion.
Q. Would you agree with me, Doctor, that it's important to -- strike that.
Doctor, did you tell your client -- your patients before using mesh on them that you consulted for Ethicon?
MS. GERSTEL: Object to the form.
THE WITNESS: Did I?
BY MR. ORENT:
Q. Uh-huh.
A. Not necessarily.
Q. Okay. Did you tell them that you consulted for AMS with regard to mesh?
A. It's within my -- my website. They have my résumé on it and everything. There are times I wasn't working for Ethicon; in fact, for most of the -- the sling years or I should say

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the -- the latter part when all this graft was, I was more of a consultant for other products for J&J, such as their nerve stimulator pieces rather than their graft materials. I did more for AMS in there -- in those time periods.
Q. And you also consulted with Boston Scientific and other mesh companies, right?
A. Just mainly giving them my opinions on what I was looking at, what I was seeing and feeling, the tensile strength, the stretchability, the -- the things that you call me as not an expert at the -- all those I -- I think I'm an expert as far as knowing what would feel good in a patient.
Q. And Doctor, you on your website believe it's important to be truthful to your patients, correct?
A. Absolutely.
Q. So, Doctor, why under mesh complications is there no information on your website?

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A. On whose complication -- there was a lot of things on that. It had listed everything --
Q. There's a lot of things on there, but there's no discussion of complications. If you click on that, Doctor --
A. Which one was it that you looked at? I had two websites. One was really old, and one was, I think, the Institute for Pelvic Medicine, I think it is.
Q. What's the new one?
A. I'll have to get it to you. My partner created it.
Q. Is that Dr. Babin?
A. Yes. It's extensive. It's -- it's in three-part harmony, got to be in there because the FDA statement's in there. So that's -- that's got it all listed out --
Q. Doctor --
A. -- in spades.
Q. -- I'm going to mark as --

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MR. ORENT: What's the next exhibit?
THE COURT REPORTER: 4.
BY MR. ORENT:
Q. -- Exhibit 4 one of the pages from your website from clinical research.
A. Uh-huh.
- - -
(Pelvic-health-surgery.com Clinical Research page printout, marked for identification as Exhibit No. 4.)
- - -
BY MR. ORENT:
Q. Doctor, do you stand by everything that you put on your website?
A. I don't monitor it.
Q. I've presented a particular statement here, and if you would, read to the jury this statement.
A. Just the headline?
Q. No, the "The FDA requested..."

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A. Where?
Q. If you go into the --
A. Oh, down below you mean?
Q. -- the body of that paragraph, yeah.
A. Besides the "...chosen to participate in AMS Elevate 522K postmarket study of Vaginal Mesh Placement in Pelvic Organ Prolapse Surgery for the FDA.
"The FDA requested some very specific follow-up studies on the placement of mesh via the vaginal route. Dr. Babin and Dr. McKinney are excited to have been chosen to participate --"
(Reporter clarification.)
THE WITNESS: "-- are excited to have been chosen to participate in these important studies. They were chosen to participate due to their experience in placing vagina mesh and the safety records as well as surgical outcomes they have

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experienced over the last decade of placing vaginal mesh in their patients. Dr. Babin and Dr. McKinney believe these studies are paramount in helping resolve the controversies that currently surround this important option for women who suffer pelvic prolapse and have risk factors for failure of a surgical repair with native tissue alone. Again, these meshes are already approved by the FDA for use in surgery and many patients have undergone this exact mesh placement over the last several years. You can feel confident about participating in the study if you are a patient determined to need a mesh for your prolapse repair as it would be the same mesh that would be used if you were not in the study."
Q. And Doctor, do you stand by that paragraph?

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A. Yes. We were actually involved in three arms of the study: Native tissue and anterior compartment as well as posterior compartment for use of the mesh. So they were given all three options to choose from and whichever they chose -- it wasn't randomized control. It was randomized as far as the patient's choice, native tissue or not.
Q. And you say, "Again, these meshes are already approved by the FDA..." Did I read that piece correctly?
A. They are already approved for use in surgery.
Q. These meshes weren't approved by the FDA prior to this, were they?
A. 522, I guess.
Q. They were 510(k). They were cleared, correct?
A. 510(k). I'm --
Q. And they were not approved for safety and efficacy -- proven safety and efficacy before this, were they?

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A. It was my thought process that the 510(k) would have been sufficient for use in surgery and, therefore, it was approved that way.
Q. Now, Doctor, did you think your patients were -- do you think your patients had the right know that there was a difference between the two?
MS. GERSTEL: Just want to put an objection on the record to the extent that we're going into transvaginal meshes at this point --
MR. ORENT: Okay.
MS. GERSTEL: -- and transcending beyond the --
BY MR. ORENT:
Q. Doctor --
A. That it is -- it's almost like a -- I consider it almost like a splitting of a hair because it is -- you're making it sound like these instruments that we were putting in or grafts that we were putting in were not

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approved through a normal process to be able to implant into patients. These were approved and they were allocated for the use.

Q. Well, Doctor, there's a material difference in what goes into a 510(k) and a 522; we -- than a PMA, correct? We've already discussed that?

A. We've done that, yes.

Q. And so my question to you is: Do -- did your patients -- did they deserve to know -- do they have a right to know that there is a difference between 510(k) and premarket approval and the processes and the amount of the data that goes into a device through each process before being implanted by you?

MS. GERSTEL: Object to form.

THE WITNESS: Well, these products have been out there for a long time with a lot of -- a lot of data that was on them, as well as for the 510(k). It's -- the

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original predecessor for these was FDA approved, and, therefore, the 510(k) was an extension of that original FDA approval. So it's kind of splitting hairs when you're saying that it wasn't FDA approved. It was a -- it was a predicate that was off of an FDA-approved material that was extended through a 510(k) approval.

BY MR. ORENT:

Q. What was the ultimate predicate?

A. Oh, God. ProteGen or something. I -- I can't -- I -- I can't remember the original --

Q. ProteGen was recalled, wasn't it?

A. It was.

Q. Uh-huh. So do you think that the patients that you put mesh into had a right to know that the ultimate predicate of the device that relieved the

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need for premarket studies was recalled? Do you think that they should have known that?

MS. GERSTEL: Object to form.

THE WITNESS: I think it should have been up to the FDA to end up not issuing the 510(k)s if they knew that there was anything different from that original predicate device. It's not for me to end up deciding on it. It's -- it was -- the FDA didn't go ahead and extend it all the way across.

BY MR. ORENT:

Q. Well, it's up to --

A. There's so much data that was out there at the time for --

Q. Well, it's up to you to inform your patients, right? You tell your patients -- you choose what you tell your patients; true?

A. I --

MS. GERSTEL: Object to

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form.

THE WITNESS: I gave them what I thought was the right information about the use of a -- a material that has been used for a long time.

BY MR. ORENT:

Q. Not in the vagina; true?

A. It's a hernia. The -- the vaginal prolapse is a hernia. There is small intestine that falls into there. There is fascial tears that creates the cystoceles, the rectoceles, the enteroceles. They're hernias.

Q. You would agree that the vagina's a different environment than the abdomen, right?

A. There is skin covering over the fascial defects just like abdominal wall has fascial defects. It's a little bit thinner material, but nonetheless, there's skin that covers over --

Q. Biomechanically --

A. -- the --

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Q. -- they're different, would you agree?
A. They come up with a lot of resistance and a lot of trauma, just like the abdominal wall can, from being punched, being hit, doing sit-ups. It's all kinds of forces that are faced on it. The whole reason why we started going to these were because the native tissue in that area was falling apart and creating recurrence of these same issues that the patient suffered, quality of life issues --
Q. Now -- now, Doctor --
A. -- tremendous --
Q. -- with -- you say that this exact mesh placed over the last several years -- you -- this article seems to indicate that Elevate has had a positive experience up to that point in time. Would you agree with me that there were no randomized control trials on Elevate at this time?
A. There were lot of series of

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case reports and that.
Q. The FDA held a panel in September of 2008 -- 2012, correct?
A. Correct.
Q. And the recommendation of the panel was to reclassify mesh as a -- for POP use as a Class III device, correct?
A. They were moving it that way, yes.
Q. And Elevate was one of those devices that was subject to this review, correct?
A. Yup, they all were.
Q. And there were a lot of questions about the safety and efficacy of POP mesh kits at that time, correct?
A. There were a lot of wanting to look, see at these things, yes.
Q. And you don't mention risk factors here. You actually say, "You can feel confident about participating in this study," right? That's what you say

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here?
A. Well, I would -- I'm saying that when I was going to end up offering these patients the -- a choice of using a graft, which I gave them the 2012 statement in there from the FDA, that they were aware of what the FDA was looking at, and that's why the 522 was being done. It was not trying to pull the wool over on patients. It's -- I was so transparent and very much aboveboard as I thought I had been all throughout my life.
Q. And so, Doctor, you told patients that the risks outweigh the benefits for the use of the Elevate device?
MS. GERSTEL: Object to the form.
THE WITNESS: As far as the risks out -- as far as failure rate, given the options, a lot of these patients -- most of them were recurrent of prolapse.

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They've already gone through it. They already know that their tissue is suspect. There are -- there are many reasons why they would end up going down those lines.
BY MR. ORENT:
Q. Did you specifically tell patients that the scientific literature shows that there is either no anatomic benefit -- excuse me, either no quality of life benefit to the mesh or no anatomic benefit over traditional measures and less complications?
MS. GERSTEL: Object to the form.
THE WITNESS: Again, there are some people that have changed their data out there and success rates and what they're looking at with native tissue versus what's going on with graft materials to expand the acceptance of native tissue repairs, and there's a lot

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of conflict in meetings over these changes. So it's rather frustrating to a lot of us that are out there.

BY MR. ORENT:

Q. So it's -- it's -- it's your -- I'm going to move on.

Doctor, you've also expressed views that you think that -- that all of this mesh stuff that we're hearing about is brought about by lawyers, correct?

MS. GERSTEL: Object to form.

THE WITNESS: I think that there's a -- there are a number of patients that do have issues with mesh; however, there are a lot of patients that have perfectly great success rates that hear over the news and all the advertisements and everything that they should have problems and they qualify for money, and I think they go hunting

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for ways in which to -- or have searched out people to take out their meshes even though they did not have an issue. And it's rather -- it's rather sickening to say the least.

BY MR. ORENT:

Q. And Doctor, how many of your patients are gold diggers like that?

MS. GERSTEL: Object to the form.

THE WITNESS: There's a company out there that was --

BY MR. ORENT:

Q. That wasn't my question. My question is specific to you. In your own personal experience, have you ever had a patient and how many patients have come to you and told you or you have believed are solely out for money and not really suffering from mesh harm?

A. I didn't say that they were looking for --

MS. GERSTEL: Objection.

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THE WITNESS: -- money as much as they get put into their head that everything and their mother can be cured if you only get rid of the mesh. I mean, I have patients come in to me with beautiful results that had rashes that got told from their dermatologist that, Unless the graft gets taken out, you're not going to get rid of your rash. They have pain in their hand, and, Oh, it's coming from the mesh in the vagina.

It -- there were a lot of very harmful things that were being put into a lot of patients, and some of them have some issues anyhow in life, and they -- they put it into their heads that they were in trouble, and yet on their physical exam by independent evaluation that they did not have anything that they thought was

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coming from their mesh, that it was coming from either their back -- they had sciatic nerve problems, they had abdominal incisional problems from old surgeries, they have adhesions, they have any number of things, they had shingles that came up. There --

BY MR. ORENT:

Q. Doctor, would you agree with me that you've explanted TVT and TVO -- TVT-O products from individuals, correct?

A. I have.

Q. And you've seen erosions, correct?

A. I have.

Q. And you've seen erosions in TVT and TVT-O cases; true?

A. Rare. They were more referrals to me.

Q. And Doctor, you've seen groin pain as a result of TVT-O, correct?

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MS. GERSTEL: Object to the form.
THE WITNESS: On one case that I wasn't able to treat conservatively --
BY MR. ORENT:
Q. And Doctor, how many mesh --
A. -- injectable, meaning --
(Reporter clarification.)
THE WITNESS: I said injectable rather than surgical, injectable in the office.
BY MR. ORENT:
Q. Doctor, how many mesh complications have you treated?
A. I -- I don't know.
Q. More than a hundred?
A. I have no idea. Probably within our practice.
Q. More than a thousand?
A. No.
Q. More than 200?
A. I have no -- I -- I can't even guess.

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Q. And Doctor, are the majority of those mesh complications that you've treated, are they from your practice or from outside of your practice?
MS. GERSTEL: Object to the form.
THE WITNESS: They were from outside.
BY MR. ORENT:
Q. And -- but you did have complications within products that you've implanted, correct?
A. Yes.
Q. And you've had erosion?
A. Yes.
Q. You've had dyspareunia?
A. Yes.
Q. Pelvic pain?
A. Yes.
Q. Failure of the device?
A. What do you mean by "failure of the device"?
Q. Failure of the device to treat incontinence; in other words,

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the surgery didn't work.
A. Yeah, recurrence. Yes.
Q. Recurrence. Well, I treat those as two separate things. But you've also had recurrence?
A. Yes.
Q. Point tenderness?
A. Yes. It's the same kind of things that would occur with pretty much any pelvic surgery that I've done through the years.
The good part about my practice is I -- probably a third of my practice is pain, and I have come up with very minimally-invasive ways of taking care of these patients, and are usually nonsurgical in etiology when you're finished with them. I do simple nerve blocks and neurolysis of the -- the -- what you're calling scar tissue, injection of these trigger points, and they all go away, probably close to 80 percent on one -- one treatment and one time through my office.

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Q. And Doctor, with the TVT, have you always used cystoscopy following the procedure?
A. Yes.
Q. That's not in the IFU, is it?
A. It's just a known thing for any incontinence procedure that we look into the -- the bladder. I mean, I train all my fellows and residents that any time that you're doing any of these surgeries, like hysterectomies, that they should be putting a scope in. It's just -- in particular, if you're a procedure where you're around the bladder, you should be looking in it.
Q. And Doctor, you've never been told by Ethicon that TVT can rope, correct?
A. Can rope? No.
Q. That it can curl?
A. No.
Q. That it can degrade?
A. No.

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Q. That it can release particles, correct?
A. No.
Q. And, in fact --
A. Have I -- have I read it, things about that? Yes.
Q. Okay. And what about chronic foreign body reaction; in your opinion, does mesh incite a chronic permanent foreign body reaction as long as the device is in there?
A. I don't believe it's a chronic problem in every single mesh. Even in your study that you looked at, when you pulled it out, there were -- less than 50 percent had chronic problems with it.
Q. I guess what I'm asking is not chronic problems. I'm talking about the actual reaction --
A. It's just an --
Q. -- you know, the --
A. -- inflammatory response that occurs, very isolated, very close to

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where the mesh is. It's not a field effect that affects and propagates throughout the entire vagina.
Q. Would you agree that it's chronic and permanent as long as the device is in there?
A. It's a -- a steady state that it's at. It's --
Q. It's not transitory?
A. It's incorporated -- the -- the connective tissue incorporates in. You get neovascularization of these grafts. It becomes the scaffold on which everything is built into, very stable, not chronically inflamed and like you'd think of anything else in the body that you had a -- an abscess or something going on in there. There's not anything close to that.
Q. But, again, it's certainly not a transitory foreign body reaction, correct?
A. It's a -- it's a reaction that happens from putting any tissue in

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in any situation.
Q. It's permanent?
A. Body kind of walls it off.
Q. And it goes on as long as the implant is in there, correct?
A. It's not a -- what you're talking about and I -- a chronic inflammatory. It's -- it's an isolated area in which -- where that -- that particular implant is, whether you have hernia areas or you have cardiovascular things, there are -- the -- the materials just are quarantined off by the body, and they are not progressive.
Q. Doctor, with regard to the TVT and Ethicon -- have you ever taught courses for Ethicon, proctored?
A. Yes.
Q. And did you receive money for that?
A. Yes.
Q. Did you receive money for teaching TVT?
A. Yes.

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Q. Did you receive money for receive -- for teaching TVT-O?
A. Yes.
Q. When did you begin teaching TVT and TVT-O?
A. I can't remember, but it's probably in the '99 year.
Q. And you did it for multiple years?
A. I did it for a few years, yes.
Q. Multiple?
A. A few years, probably two, maybe three. I don't -- I'm not sure exactly.
Q. And you would agree that TVT and TVT-O, regardless of the rates and regardless of whether they're defective or not, they can cause permanent injury to some women; there are some small -- there's some universe of women, however big we can debate, that are permanently injured by mesh --
MS. GERSTEL: Object to the

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form.
BY MR. ORENT:
Q. -- including TVT and TVT-O, correct?
A. I think that there are any pelvic surgeries or incontinence surgeries that can end up leading to problems, including death from doing nongraft material cases, probably more from -- from Burches where they've gotten into the obturator vessels and caused --
Q. Okay. That's --
A. -- all kinds of --
Q. That's not my question. My question's --
A. I know.
Q. -- just to TVT and TVT-O. Would you agree that there are patients out there who are permanently injured by these devices?
A. I think there -- there are patients that have been affected by a surgical procedure for incontinence, which happened to be TVT or TVT-O.

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Q. Okay. Do you agree that the vagina is a clean contaminated space?
A. Well, it is a clean contaminated space. Hmm. That's an oxymoron if you put it that way. There's always bacteria in the vagina.
MR. ORENT: And I think that's about it, Doctor. Why don't we take a break. I'm just going to go over my notes here, but I think I think we're about done.
(A recess was taken from 1:46 p.m. until 1:59 p.m.)
- - -

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EXAMINATION
- - -
BY MS. GERSTEL:
Q. Dr. McKinney, my name is Diana Gerstel, and I'm from the Riker Danzig firm, and we represent Johnson & Johnson and Ethicon in the pelvic mesh litigation.
You've been asked some questions by plaintiff's counsel, and I'm going to ask you some follow-up questions. Are you ready to proceed?
A. Yes.
Q. Dr. McKinney, is it your opinion that the 2015 TVT IFU adequately warns physicians of the potential risks of the device?
A. Yes.
Q. And is it your opinion, Dr. McKinney, that the versions of the TVT IFUs that existed before the 2015 version also adequately warned surgeons of the risks of the device --
A. Yes.

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MR. ORENT: Objection.
BY MS. GERSTEL:
Q. -- devices, I should say?
A. Yes.
Q. And what is the basis of your opinion that the IFUs adequately warned surgeons of the risks of the TVT devices?
MR. ORENT: Objection.
THE WITNESS: Well, the IFU is designed to basically cover the basic premise of what can happen with it and particularly the uniqueness of the -- the actual device, and the majority of things that are standard to all surgical procedures and particularly for that area should automatically be note -- known by physicians that are operating. And whether they be urologists, gynecologists, colorectal surgeons, they should all have knowledge of that -- that aspect.

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So having the -- what was in the original IFU was sufficient enough.

BY MS. GERSTEL:

Q. Does your opinion as to the adequacy of the warning information in the TVT IFUs -- is that based in part on your experience as a surgeon?

A. It's definitely based on my experience as a surgeon. Obviously, it's extensive. I've gone through training in medical school, residency, and fellowship training. All throughout the time period you're taught how all these surgeries affect different areas, and so the IFU's just in addition to your own knowledge base of what a surgical procedure would entail and what could potentially happen. So the IFUs just cover what is peculiar to that individual device.

Q. Is your opinion also based on your experience as a faculty member of a medical school and a residency program?

A. Yes.

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Q. And is your opinion also based on your review of medical literature?

A. Yes.

Q. Who are the intended users of the TVT IFUs?

A. The intended users are the -- the surgeons involved with it, the staff within the OR, and anybody else who wants to end up praising themselves of the --

(Reporter clarification.)

THE WITNESS: -- who is looking at the use of that device.

BY MR. GERSTEL:

Q. Is the IFU the sole source of information that surgeons have as the -- strike that.

Is the IFU the sole source of information that surgeons have as to the risks of the TVT devices?

A. There's numerous places where we all get our information from. I hope not everybody is just looking at the

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IFU. You've got to have gone through some form of formalized training or at least looked at where these devices are and what their uses are and where it came.

And they come from meetings. They come from doing different courses where there could be hands on, either cadaveric or these models for placing the -- the actual devices in. They were readily available for people to be trained on so that they're not the first time using it -- using it on a patient, or at least you would have a preceptor either coming in with you or to work with you and guide you through, or you were going into somebody's OR that was knowledgeable of the device to be able to ask the questions and pick their brain and understand and see what was going on beforehand.

Q. Do surgeons also learn about the risks of the TVT-O devices in residency and fellowship?

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A. They definitely do at this point in time, obviously. Before 1998, mainly over in Europe, maybe they did -- or '97 I should say, but in the States it was just coming about. But after '98, it was definitely taught in your residency program, in your fellowships, absolutely.

Q. Is pelvic pain a risk that is associated with all stress urinary incontinence surgeries?

MR. ORENT: Objection.

THE WITNESS: Pelvic pain is associated with all reconstructive surgeries, including incontinence procedures.

BY MS. GERSTEL:

Q. Is dyspareunia also a risk of all stress incontinence surgeries?

A. Yes.

Q. What are other risks that are risks of the TVT devices that are also risks of all other stress incontinence surgeries?

A. Death, infection, injury to

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any of the surrounding structures, bladder, bowel, nerves, ureters, bleeding. And particularly, there can be suture erosions just like there's graft erosions, damage to the urethra, recurrence of the incontinence or just failure of the procedure, itself, can end up doing it. So that's a large number of the -- the risks.

Q. The pelvic pain and dyspareunia which are -- well, strike that.

Is pelvic pain also -- is chronic pelvic pain also a risk of all stress urinary incontinence surgeries?

A. Chronic pain, yes.

Q. And that would include dyspareunia, chronic dyspareunia?

A. It would include dyspareunia. It would include in some instances -- I know when we were doing Burches with -- with permanent suture materials that there would be even some hispareunia because of the pile of

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surgical suture material that would be palpated through the periurethral area.

Q. What is hispareunia?

A. It means pain when a gentleman puts their penis into the vagina.

Q. Doctor, would you agree that the mesh in the TVT devices is a macroporous lightweight polypropylene mesh?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MS. GERSTEL:

Q. And Dr. McKinney, do you agree that the TVT devices have been demonstrated in the medical literature to be safe and effective in women for the treatment of stress urinary incontinence for up to 17 years?

A. Yes, Nilsson's paper in particular.

Q. What is your opinion as to -- well, strike that.

Have any other meshes, other

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than the mesh that is used in the TVT devices, been studied for as long a period of time for the treatment of stress urinary incontinence as the mesh in TVT devices has been?

MR. ORENT: Objection.

THE WITNESS: No.

BY MS. GERSTEL:

Q. Has the safety and efficacy of the TV -- of TVT been studied in multiple long-term studies?

A. Yes.

Q. And has the safety and efficacy of TVT-O been studied in long-term studies?

A. Yes.

Q. Is it desirable to surgeons such as yourself that the TVT-A -- T -- excuse me. Strike that.

Is it desirable to surgeons such as yourself that the TVT and the TVT-O have been studied in multiple long-term studies?

A. Absolutely, yes.

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Q. And why is that?

MR. ORENT: Objection.

THE WITNESS: Why having it -- the data out there? Because it's very helpful in educating our patients, as well as giving us more of a comfort level for the use of the device, especially in the environment that we're in right now.

BY MS. GERSTEL:

Q. Dr. McKinney, is it your opinion that reliable data does not show degradation or that there is a clinically-significant long-term chronic inflammatory effect of TVT?

MR. ORENT: Objection.

THE WITNESS: I'm sorry. Can you read it again?

BY MS. GERSTEL:

Q. Yes. Dr. McKinney, is it your opinion that reliable data does not show clinically-significant degradation associated with the TVT devices?

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A. Yes, there isn't good, tight data. So, yes, no.
Q. Dr. McKinney, in other words, there is no reliable data showing that degradation of the mesh in the TVT devices occurs to any degree that has a clinical impact on patients; is that true?
MR. ORENT: Objection.
THE WITNESS: That there is -- clinically, there is no evidence that there is a breakdown or degradation of the mesh material or any cytotoxicity.
BY MS. GERSTEL:
Q. Is it also your opinion, Dr. McKinney, that reliable data does not show there is a clinically-significant long-term chronic inflammatory effect of TVT on patients?
MR. ORENT: Objection.
THE WITNESS: That is correct.
BY MS. GERSTEL:

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Q. Dr. McKinney, are TVT and TVT-O the gold standard and the standard of care for treating stress urinary incontinence?
A. Yes.
MR. ORENT: Objection. I'm sorry.
BY MS. GERSTEL:
Q. What is the range of overall care and improvement rates for TVT? Can you say what the -- well, strike that. Let me ask that a better way.
Can you tell us what is the rate of overall care and improvement of SUI after implantation of TVT or TVT-O?
MR. ORENT: Objection.
THE WITNESS: Depends upon which study you're looking at, but if you look at the 17-year data, I guess, from Nilsson, I think it was like 91 percent or something for objective, and subjective was 87 percent. But I'd say in all the papers that you read, it can

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range anywhere from around 80 percent up to 94 percent.
Serati's data for ten years was about -- subjective was 89, 93 was objective, and urodynamic cure was 91. So that's a pretty significant, good paper that was out there.
BY MS. GERSTEL:
Q. And Dr. McKinney, what is the range of mesh exposure rates that are seen in -- after implantation of TVT or TVT-O?
MR. ORENT: Objection.
THE WITNESS: Very low. I think I put it in here somewhere. 1.5 percent was roughly the rate for TVT and I believe it's roughly the same for TVT-O.
BY MS. GERSTEL:
Q. Can most mesh exposures that occur be conservatively managed?
A. Absolutely, yes.
Q. And --

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MR. ORENT: Objection.
BY MS. GERSTEL:
Q. -- what does conservative management mean?
A. As little as just being applied estrogen therapy, estrogen cream tube, and if there are trigger point pain areas, they can end up being injected with a local to break up some little scar tissue that may be around it and then inject it with a neurolytic. I use five percent sodium hydrochloride, knocks out the nerve that may be involved in it.
But for the most part, we use just hydrodissection and a localized steroid into the area to decrease the inflammation from the -- the irritant and it's sufficient enough to go away. Physical -- physiotherapy, massage of the -- the, you know, muscles and conservative therapy that way.
Q. Dr. McKinney, can you say what percentage of TVT and TVT-O surgeries are associated with -- strike

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that. Let me start that over.
Dr. McKinney, can you say what -- in what percentage of TVT and TVT-O surgeries is the complication of pain or dyspareunia seen?
MR. ORENT: Objection.
THE WITNESS: The -- it's minimal from the -- the actual slings. I believe it's somewhere in the 1 percent range or less.
BY MS. GERSTEL:
Q. Is the rate of dyspareunia and pain higher with the Burch procedure?
A. I would say yes, absolutely.
Q. And is it higher with autologous fascial slings?
A. Absolutely.
Q. And the information you're providing as to rates of complications, is that based on -- what is that based on?
A. Well, if you even look at the rates just for the sister study with the Burch and the pubovaginal slings,

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they reported upwards of -- overall adverse events were higher with the fascial sling procedure with it being 63 percent of the cases done had adverse events versus 49 percent in the Burch group just between -- everything from pain to voiding dysfunction, urinary tract infections, and the success rates were definitely much poorer in that series study and declined over time, whereas TVT slings and the obturator slings did not really decrease and deteriorate in their success rates.
Q. The rates of complications that you are citing from the medical literature, are those consistent with what you've seen in your own practice?
MR. ORENT: Objection.
THE WITNESS: They are, I think, a little bit higher than what -- even from my practice. But, obviously, that was one of these major studies that got sponsored, I think by NIH. When

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I'm looking at these, and it was published in New England Journal to begin with, I think there was subsequent reporting of that in long-term aspects in the Journal of Urology, as well.
So it's definitely -- those procedures are very invasive. They're very risk-apparent. I've had to do a lot of takedowns of slings because -- and to do a release for retention from a -- that little midurethral tape is a pretty simple procedure. You just have to cut the sling and you're pretty much done for your urethrolysis.
When you have one of these major retropubic procedures that you have to do, it's a major dissection of that entire anatomy around the urethra. There's risks of perforating into the bladder, into the urethra, and it is very

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difficult to keep it from re-adhering into that space.
So it's -- it's not -- it's not a fun procedure. It is hours and hours and hours of whittling away at the anatomy in there and also causes you to disrupt the nerves to the urethra when you're doing so, so high probability that you're going to have a recurrent or worse incontinence situation after you've done the release versus with a sling. It's almost, I think, 90 percent of those patients that you release it are going to still be successful.
BY MS. GERSTEL:
Q. Dr. McKinney, have TVT and TVT-O been recognized as safe and effective by numerous medical societies?
MR. ORENT: Object.
THE WITNESS: Yes, just about every single reputable one in the world, including NICE,

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including IUGA, International Continence Society, all the ones in the US, SUFU, AUGS, American College of OB/GYN, the American Urology Association, the surgeons -- the surgical societies. I don't think there's a single one that hasn't acknowledged that this is the standard.

BY MS. GERSTEL:

Q. You were asked some questions this morning about the AUGS/SUFU position statement. I think it's dated January 2014. And the -- that position statement has recently been updated; is that correct?

A. That is correct.

Q. And that updated AUGS/SUFU statement, which I believe the date of that update was June 23rd, 2016, that position statement was, itself, endorsed by a number of other medical societies; is that correct?

MR. ORENT: Objection.

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THE WITNESS: Pretty much every one that I just have mentioned has endorsed that -- that statement, position statement.

BY MS. GERSTEL:

Q. Was it also endorsed by patient advocacy groups?

A. Yes.

Q. And do you know --

MR. ORENT: Objection.

BY MS. GERSTEL:

Q. -- which ones those were?

A. What's the -- it's the urological nursing piece and it's an incontinence group. Can't remember.

Q. Is it NAFC?

A. Yes.

Q. And WHF?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MS. GERSTEL:

Q. And do you know what those stand for?

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A. The -- I'm sorry. The -- the first initials were?

Q. NAFC.

A. National Association For Continence, I believe. I know the woman that runs the thing or started it, anyway. I don't know if she's even still alive. I -- I can't remember. Sorry.

MR. ORENT: Just off the record.

(Discussion off the stenographic record.)

BY MS. GERSTEL:

Q. Dr. McKinney, you were asked some questions about your own consent process with your patients in whom you implanted mesh products. When you engaged in a consent discussion with your patients, did you engage in a discussion with them as to the risks and benefits of the mesh product at issue that was tailored to each patient?

A. Yeah, it was an extensive time period that I gave them to end up

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understanding the risks, complications. I had pictures on the wall in which I described what their defects were, what I was planning on repairing, where these things were going to end up going. I had a box of the implantable devices that were sitting there so that they could have their hands on them, touch them, feel them, understand what I was putting in them.

But it was very extensive, and like I always said, I always started with the worst complication first; you could die. Of course, I'd joke to them, and I'd say, Well, but I'll -- I'll kill you if you die. But it's -- pretty much sets the tone for how extensive I got in -- in the definition. And it was always typed out at the bottom of my consent forms, perhaps it was overkill, everything to do with graft material, erosions and pain and failures and injury --

(Reporter clarification.)

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THE WITNESS: -- and injury to all the surrounding structures, and I'd list a litany of everything that could potentially be in there.
BY MR. GERSTEL:
Q. Dr. McKinney, has any reliable data demonstrated any clinically-significant difference between outcomes with laser-cut mesh and mechanically-cut mesh?
A. There have not.
Q. Dr. McKinney, you were asked about Ethicon company documents. Did you read Ethicon's patient brochures for the TVT products?
A. Yes.
Q. And did you rely on them?
A. I usually would give them out to the patients, but I didn't completely rely on them myself because I knew what was going on. But I utilized them as far as helpful to educate and understand and teach other people that I

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was teaching.
Q. Dr. McKinney, were you -- well, strike that.
Did you read the TVT Surgeon's Resource Monograph?
A. Yes.
Q. And did you have a role in drafting that document?
A. Yes. There was a group of us that got together, and we sat and put together what we felt were the pertinent education pieces that we learned through that time period at the beginning of when TVT and TVT-O were -- or actually, it was just TVT at that time -- were propagated so we could minimize the learning curve for anybody doing these procedure that would -- we -- we took our experience and put it in there as -- as our best way of approaching each of the sections.
Q. And what's been your experience with IFUs for mesh products as a surgeon?
A. From the IFU aspect, other

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than reading the IFU, I have had experience writing IFUs, myself, so it's -- again, it didn't impress me one way or another. It was just a -- what I thought was adequate to understand the -- the actual TVT or TVT-O when I read them.
Q. Are you experienced as a -- as a -- strike that.
Have you as a surgeon read the IFUs for a number of different medical devices?
MR. ORENT: Objection.
THE WITNESS: Yes. I've read them for pretty much the -- the Bard products, the Boston Sci products through the years, pretty much, probably hundreds of them.
BY MS. GERSTEL:
Q. And you alluded to this earlier, but I believe you testified that you also have experience as the writer of IFUs as well; is that correct?
A. I have.
Q. And could you tell us about

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that, please.
A. Well, for my -- for my products -- I've had to work creating the IFU for my diagnostics products for urodynamics and multiple different products. Worked with my regular -- regulatory department to end up putting those together, as well as the CR reports, and obviously had some guidance from regulatory, but definitely more experience probably than the majority of my fellow surgeons out there just because of that.
Q. Dr. McKinney, do you have expertise in handling and placing the mesh in the TVT devices?
A. I'm sorry. Could you repeat it? My -- my stomach was making a --
Q. Dr. McKinney, do you have experience in handling and placing mesh in TVT devices?
A. Yes.
Q. And have you followed your patients' outcomes after placement of TVT

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devices in those patients?
MR. ORENT: Objection.
THE WITNESS: I -- I have and my fellows have looked at the outcomes for pretty much all my pelvic floor surgeries, as well as for incontinence, and we do follow these patients on a regular basis and have questionnaires that the patients had to fill out going along with what their surgical outcomes would be.
BY MS. GERSTEL:
Q. As a faculty member of a medical school and residency program and, I believe, a fellowship program --
A. Yes.
Q. -- were you required to continually assess your and your trainees' outcomes with TVT devices?
MR. ORENT: Objection.
THE WITNESS: We looked at our data pretty -- pretty closely to make sure that it was in tune

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with what the -- the rest of the literature was out there. We had periodically some presentations that we had to do within the department to talk about these.
Any major complications ended up coming in and would be reported for an M&M, or mortality and morbidity conferences. Fortunately, not -- not too many in my lifetime have been needed to be brought out for review.
BY MS. GERSTEL:
Q. In addition to being knowledgeable of the medical literature on the history of stress urinary incontinence surgeries, were you personally knowledgeable of the history of the different kinds of stress urinary incontinence surgeries?
MR. ORENT: Objection.
THE WITNESS: Obviously, my longevity in life has enabled me to see the evolution of

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incontinence surgeries from its primitive beginning, I think, with doing the Kelly plications, which had a 37 percent success rate, but at the time when I was learning, that was the standard.
Needle suspensions I learned because most of the urologists were doing the Pereya or Raz, and every year I was wondering why Raz had modification of the rods, even though he had a hundred percent success rate at the one-year mark. Adoni had a 42 percent. The Burch, which was what I was taught, had about an 82 percent five-year success rate from Bergman.
And this whole series of episodes, I -- I got to witness the -- and that's what I was taught as my backup was the Burch, and then the retropubic sling was like last resort where we'd end up

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either taking and harvesting rectus fascia, or we'd harvest off -- the fascia lata off the leg.
I did a lot more of the harvesting off the leg in Africa for patients there for their incontinence because we were dealing with fistulas and risks of the urethra having problems. So we'd -- and if they had leakage, even if we repaired the fistula, we knew that they wouldn't be able to return to their villages unless they were continent.
So at the same time as we'd repair these holes and they were at risk for if we put materials in them such as a TVT, we'd have a higher risk of erosion, and we'd use autologous material in those cases.
So I've had a lot of experience with use of those

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autologous side of things, as well, and I got to see uses of Mersilene from, I guess, the Mayo Clinic people that taught me. I had Glenn Hurt utilizing cadaveric fascias for replacements and for slings, and those -- the data came back that they were being chewed up and spit out and the failure rate was too high. There was use of Gore-Tex for these things, and that was encapsulated and problematic.

So, yeah, through the years I saw a lot of the development of all these different procedures. I had treated with a laparoscopic Burch utilizing a hernia mesh, Prolene Soft lateral to the urethra, stapled it on and up to Cooper's ligament for -- it was a hernia repair for the incontinence procedure, and that was in the early '90s, as a way in which to

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get more people to be able to repair these laparoscopically rather than throwing sutures, which was really cumbersome and difficult.

So, yes, I participated in and moved that through. And then the TVT came along and there was no need for doing that type of a procedure anymore, so it kind of lost favor and found it so much easier for the patient and for me as a surgeon to end up doing a TVT than it was to do all these major invasive constructions, which you could throw stitches.

You had so many risks there. They'd pick up a ureter and tie it off, you could throw stitches into the bladder, you can obstruct things, you can tie them too tight, you can -- your retractors can be right on the obturator nerve, artery, and vein, and there

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was notoriously veins coming out of the obturator canal and up over the bone structure so whenever you were retracting, you oftentimes got a -- a cascade of blood coming down from it.

So, yes, there was -- I lived the transformation of incontinence procedure and was relieved when TVT, TVT-O, retropubic slings from all companies came about.

BY MS. GERSTEL:

Q. Dr. McKinney, among the Ethicon documents that you reviewed, were there documents pertaining to laser-cut mesh -- the use of laser-cut mesh versus the use of mechanically-cut mesh?

A. There were some documents in there of the -- that there was laser cut, and then there was the straight cut. So, yes, I am aware of those.

MS. GERSTEL: That's all I have.

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FURTHER EXAMINATION

- - -

BY MR. ORENT:

Q. Doctor, just some follow-up questions on what counsel just asked you.

First of all, you're talking about your -- your follow-up with patients and your tracking of your data. Do you remember those questions?

A. Yes.

Q. What's the lost follow-up at one year for your TVT patients?

A. Fortunately, not very high, because my practice is mainly -- or at that time was mainly from the local area, from down the Jersey shore, over to Pennsylvania area and up. So we made them come back at basically six weeks, three months, six months, and a year, and then yearly thereafter. So it was a pretty good follow-up on those patients.

Q. And for how many years did

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they have to come back yearly?
A. For as long as I could possibly get them to come back.
Q. So you felt for the TVT device, it was important to have them come back annually?
A. I felt it was -- for any kind of reconstruction work for what I was doing with my fellows, it was important for them to see the -- the follow-up.
Q. And in regard to the Ethicon TVT product, does it say in the IFU that follow-up should be done on an annual basis each and every year following implantation?
A. Does not.
Q. Okay. What was your partition [sic] rate after one year -- between one and five years in terms of the aggregate data that you have between 1998 and 2015?
A. I -- you got to repeat that again, I'm sorry --

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Q. Sure.
A. -- what your --
Q. Between --
A. -- specific question is.
Q. Sure. Between years 2 and whatever, 1998, you know, the entire cohort of patients that you've had, what's your participation rate from two years forward in terms of follow-up?
A. My participation rate in following up and making sure that they -- they came in? I told you it was -- it was high.
Q. Right. But how many of those patients actually came back at year two; how many came back at year three; and what percentage drop-off between years two and three did you see?
MS. GERSTEL: Object to the form.
THE WITNESS: It was significant. It dropped off just from attrition.
BY MR. ORENT:

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Q. Would you agree that the most significant drop-off was between year one and two?
A. No, two and three.
Q. Two and three? Okay. Would you agree that Ethicon does not suggest that follow-up be done at year -- at two years or three years on post-op in the IFU?
A. Well, the -- the most part, the reason why I would have patients come back in is for my own self-edification and for the fellows' follow-up. It was not something -- I think most of these patients that dropped out had no problems and so they didn't see a reason why they needed to come in, especially when they didn't have a uterus or they're going to see their regular gynecologist.
I had fellows calling me to give a questionnaire to see whether or not they had failed or not, and so --
Q. Well --
A. -- most of them that didn't

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come back actually had --
Q. Okay. So over --
A. -- good results.
Q. Over your entire career, what is your -- what is your complication rate -- your aggregate complication rate at five years?
A. For graft materials?
Q. TVT and TVT-O, specifically those branded products.
A. Okay. For anybody that had to go back to the OR was probably less than 1 percent.
Q. I'm not asking probably. I'm asking to a -- to an actual number, what is the aggregate complication rate for each -- for all of the complications with TVT at five years. Not just recurrence -- excuse me, not just reoperation, but your complication rate.
A. Less than 2 percent.
Q. And what is that based on?
A. It's based on an aggregate of who I had to bring back to the OR, any

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pain that was there, any kind of exposure of graft materials.
Q. And how many patients fall into this study?
A. Again, this is non -- non-reported materials. It wasn't peer reviewed or anything, but it's just what we ended up looking at to --
Q. Right. Well, what I want to try and understand is if you're going to testify to data --
A. Yeah.
Q. -- and tell the jury 2 percent, I'm entitled to know the basis of that 2 percent complication rate. So what I want to know is how many patients 2 percent equals.
I want know when those patients experienced complications, whether they were most common within one year, between years one and five. I want to know what the follow-up is after five years. All of the types of things that would be reported in peer-reviewed data I

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want to know.
And so as you sit here today, are you prepared to answer those questions in that kind of detail?
MS. GERSTEL: Object to the form.
THE WITNESS: I'm probably more inclined to go from the literature side that was peer reviewed than to come off of that data, even though I -- I was pretty proud of the fact that I did follow those patients.
BY MR. ORENT:
Q. I understand that.
A. Uh-huh.
Q. Now, you also were asked some questions about the IFU, correct?
A. Yes.
Q. And you mentioned something. You mentioned, actually, a couple of things. You mentioned that the basic premise was that in an IFU, it's your opinion that not all risks should be

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shown, but the unique risks of a device should be known -- should be stated in the IFU; is that right?
A. Yes.
Q. And would you agree with me that when TVT was launched in 1998, the vast majority of doctors between 1998 and 2007 that were using TVT hadn't had a lot of experience using other graft -- artificial synthetic graft materials prior to TVT?
MS. GERSTEL: Object to the form.
THE WITNESS: That's kind of up in the air, but -- because there were a lot of graft materials being used, pledgets. There were all kinds of things by urologists being used that were --
BY MR. ORENT:
Q. Would you agree that TVT sort of opened the floodgates to polypropylene mesh as -- utilized as a tape midurethral sling with the Integral

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Theory for this treatment of stress urinary incontinence?
A. Yes.
MS. GERSTEL: Object to the form.
BY MR. ORENT:
Q. And that doctors previously hadn't used a midurethral sling in the way that TVT had been used originally in 2008 in the United States?
A. Yeah, it was a different --
MS. GERSTEL: Object to the form.
THE WITNESS: -- philosophy from the use of slings in the past. We're more towards the support of the urethra/vesical junction rather than the midurethra, although Tanagho believed that the mid -- his modification of the Burch was a midurethral stitch there. He thought that that stitch was the most important because that's

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where the maximum urethral closure pressure was and the most -- closest to the anatomical defect that he thought was there, which was a tear of that pubourethral ligament.

So that's where the midurethral sling and the Integral Theory and Tanagho's thoughts -- thought process in the incontinence procedures that developed --

BY MR. ORENT:

Q. And up till 2014, there was no boarding for urogynecologists, correct?

A. '13.

Q. '13, sorry, there was no boarding for urogynecologists, correct?

A. There was not a formal board. No, there was not.

Q. And there were -- wouldn't you agree that that first generation of folks using TVT were entitled to know

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about the nature and severity of complications with synthetics that they previously hadn't been exposed to?

MS. GERSTEL: Object to the form.

THE WITNESS: I don't know what you're trying to drive at, but it was pretty well known that there were risks and complications to any kind of surgical intervention. Any time that you're using a permanent material, suture or otherwise, you had risk of it showing up, and it was known to most of these physicians that there could be issues.

BY MR. ORENT:

Q. Do you agree that a doctor should be able to rely on an IFU, once it's already printed, that the doctor should be able to rely upon it for contraindications?

A. I'd say that probably only about 10 percent even read the IFUs.

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Q. But do you think that it should be truthful and reliable when it's out there?

A. I think that it --

MS. GERSTEL: Object to the form.

THE WITNESS: -- should be a useful piece of information to end up reading through and understanding how to use the device and what the -- the side -- sideline activity or misadventures could be.

BY MR. ORENT:

Q. And so you would agree that when material is in an IFU, which would be -- in terms of contraindications, a doctor should be able to rely upon that?

A. They should be able to read it and understand a general concept of what can potentially happen.

Q. And should a doctor who reads an IFU be able to understand the warnings in the IFU?

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A. Should be able to.

Q. Okay. And for TVT, in fact, the -- when TVT was brought over to the United States, the cohort that had the 17-year experience was done in Europe, correct?

A. Nilsson.

Q. And, in fact, the procedure or the implant technique that was used on those folks was actually different than the implant technique used in the United States, correct?

A. Not -- it all depends.

Q. Well, the -- let me ask you this: The original implant technique in Europe was done with the patients awake, correct?

A. A lot of them.

Q. And --

A. Some were even done with spinal anesthesia, so that's --

Q. Well, that's -- that was going to be my next question.

A. Yeah.

Q. And that was designed --
A. It was a different --
Q. -- for tensioning of the device, correct?
A. The spinal, I had a problem with them doing it that way, but it was more for the passage of the needles to make sure that the patients were in position. It also had something to do with waking them up and having them participate, yes.
Q. And that was -- important in the original study was -- the proper tensioning of the device done while the patient was awake allows the doctor to know that the doctor has left the device tension free, but also that it's preventing incontinence from occurring, correct?
A. Well, if you fill the bladder over there, yes. If you did a cough stress test associated with it. We can do that in the States, even if you did use general anesthesia or a form of

it. You can have the anesthesiologist wake them up, bring them light and -- and/or have them gag on their -- their ET tube.
Q. But that's not done in the United States typically, correct?
A. Well --
Q. It's not in the IFU?
A. -- again, there -- there's a lot of slings that were done in Europe that weren't just slings. They were also concomitant surgeries and that --
Q. Well, I --
A. There were confounding factors that are involved in a lot of these, particularly in the US, too.
Q. I understand that.
MS. GERSTEL: Can I ask what our time is?
(Discussion off the record.)
BY MR. ORENT:
Q. So, Doctor, would you disagree with me that that original procedure is different than the

procedure that's in the TVT IFU that was brought over into the United States?
A. Not necessarily. It was -- there's multiple variations of doing it. That's fielder's choice, and I've -- I've done it the way it's done over in Europe. That's a lot of way I -- in which I taught mine. But when I've got general anesthesia for other procedures and obviously trying to bring them out to make them lighter or have them gag on their tubes and -- there -- there's been so much data coming out on when you do spinal injections, whether it changes the pelvic floor. They're paralyzed, so what good is it to -- to have them cough if their pelvic floor isn't going to work anyway? So, yes, lots of -- lots of variations.
MR. ORENT: All right. I have no further questions. Thank you, Doctor.
(Deposition concluded at 2:52 p.m.)

C E R T I F I C A T E

I HEREBY CERTIFY that the witness, TIMOTHY B. McKINNEY, M.D., was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before the completion of the deposition that the witness, TIMOTHY B. McKINNEY, M.D., have the opportunity to read and sign the deposition transcript.

CONSTANCE E. PERKS, CRR, CLR, CRC, RSA
Notary Public I.D. #2381708
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Dated: July 8, 2016

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After doing so, please sign the errata sheet and date it.

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It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages (1 - 185) and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____

TIMOTHY B. McKINNEY, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

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